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☐ *Additional inventors are being named on the ___ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

Safety Suture Needle Assemblies and Means of Activation.

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Respectfully submitted,

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Titl :

Safety Suture needle assemblies and means of activation.

Background-Field f inv ntion:

This invention relates to safety needle systems, to prevent the transmission of body fluid borne pathogens to personnel conducting medical procedures with sharp objects, in particular suture needles, and also unwanted punctures of the sterile surgical environment caused by sharp medical objects. The embodiment of the needle itself is composed of a Shape Memory Alloy Mechanism (SMA). The activation for the present SMA mechanism is achieved by Ohmic, or thermal heating of the SMA material, using new and existing means.

Surgical needles have been used for centuries to close biological tissue that has been separated either by trauma or surgical procedure. The surgical needle is used to penetrate tissue for the advancement of a suture material in order to approximate the abrupted biological tissue, in order for the natural healing processes to occur. The surgical needle itself has a sharpened end, with various sharp tip configurations for the desired effect or particular tissue. The needle body is made of mainly high strength steel, and is formed to many dimensions, shapes, and wide variety of means for attaching the suture material including gluing, crimping, swaging, utilizing shrink wrap type material and so on. The needle is sterilized and packaged according to known and widely used means as to reduce the chance of infection of the surgical or wound site.

The standard surgical suture needle is dangerously exposed to surgical personnel and the surrounding environment, increasing the chances of accidental puncture. Because of the said needles size, it is often hard to "track" during surgical procedures, it is also freely handled manipulated, and positioned at difficult and dangerous angles in reference to its sharp tip. Because of the forces exerted on the needle at particular points during a surgical procedure, and because of the inability to visualize the sharp needle point, it poses a significant hazard to medical personnel.

The surgical needle itself after it is introduced to the sterile surgical environment, is at

once considered a hazard due to the presence of its sharp exposed tip. Other devices such as trays, magnetic holders, and cushioned beds for the needle have been introduced, but are not always utilized due to the fast paced and sometimes chaotic surgical environment. Often needles are rested in unsafe locations, and then pose a hazard that the other said means are not able to minimize.

Background-Prior Art:

Prior attempts at designing a safer suture needle have been attempted, in particular Patent Number 5236443 to Sidney Sontag (1993), and also patent number 6159233 to Yuichi Matsuzawa (2000). The problems with engineering a safety suture needle, are impart due to its extremely small size, and intricate and complicated manufacturing processes. Sidney Sontag's patent, utilizes a wire ridge like projection that extends from the top middle portion of the needle body itself. The idea of the needle is that when the needle is held in a needle holder, the wire ridge is depressed, which in turn results in an otherwise sheathed sharp tip protruding from the needles distal end, rendering the otherwise blunt needle sharp. I see two faults with this concept, one being the ridge that is formed from the wire exerts additional unwanted dilation upon the tissue that is being penetrated, two, the hollow distal blunted end, still poses a puncture hazard similar to that of a hypodermic needle.

Yuichi Matsuzawa's patent poses the concept of utilizing a surgical needle type device with a blunted projection tip, that operates on the same principles as an electrocautery unit. The idea is that as the needle device passes through tissue a high frequency current passes through the embodiment and locally abrupts tissue about the needle embodiment thereby making passage of the needle more easy to facilitate. I see three faults with this concept. One being, it is not always realistic to have an extensive assembly with the said electrocautery unit available, particularly in minor laceration repair say within an Emergency Department, or within field operations such as during Military operations. Second, the properties exerted from the electrocautery like mechanism are arguably not always ideal, for example on tissues that are extremely delicate or may otherwise be harmed from the cauterization properties of the said

mechanism. Third, the hollow distal end still poses a puncture hazard similar to that of a hypodermic needle.

Additionally the use of general suture needles with a blunted tips, have been utilized for the closure of various tissues, however such a blunted needle is not always realistic when closing tissue of a denser consistency and the force that is exerted poses an additional hazard to the medical personal and or patient. Such force exerted with this type of needle can also induce additional unnecessary trauma to the tissue.

Other attempts have been made, but the above two references are the most similar to the current invention, within the conducted field of my search of prior art. These and other safety suture needle concepts have been introduced to the public domain, but according to my research none have made a significant impact on the occurrence of suture needle sharp stick injuries, except for the blunted tip needle where it is not always applicable to use in a variety of procedures. The reason, I feel, for the lack of incorporation of the prior art, is due to the complexity of said inventions, the disadvantages listed, and the education of medical personnel to take proactive measures to heighten their awareness of the location, position, and disposal of said sharp objects. Ultimately no accidental punctures is the goal, and in addition to the known widely practiced "standard precautions" that are currently utilized, a safer needle with a sheathing or blunting shield I feel could almost completely eliminate accidental punctures, except in the case of some unseen event.

An additional problem exists with suture needles in that due to their relative size, material shape, and the forces sometimes exerted on them, they can break or snap under certain conditions. Several patents reference the idea of using a central relatively pliable shaft, that in case of accidental breakage, holds the external broken pieces of the needle body together so as to not allow the broken pieces to fall within the particular body tissue, and perhaps be lost in the tissue. The present inventions internal mechanism and construction fulfills this concept, by having all pieces attached linearly along the axis of the needle body, so that by natural occurrence if such a force was applied upon the needle to the point of breaking, the internal

contents would keep the external body of the needle together so as to prevent the loss of the broken parts into the tissue.

General Descripti n and abstract:

A general figure for the typical embodiment of the present invention is illustrated in figure 1. The body as a whole is designed for the penetration of tissue and utilizes a mechanism for the blunting of the sharp distal end figs 3-8. The said embodiment is activated by an external source fig 2.1A, 2A, (other) by using a Shape Memory Alloy (heretofore referred to as "SMA") material assembly of various said and illustrated concepts. The variation in concepts is due to the small size of the said assembly, and difficulties in manufacturing and assembling of pieces at this small scale. The variations presented are all applicable and could be utilized depending on manufacturing techniques, and consumer preference. Generally 2 designs showing utilization of the properties of the SMA in this context. Mainly, one being the characteristic of "Nitinol" a nickel titanium alloy, to contract when heated either directly or by ohmic heating through the passage of a nominal electrical current, The second general property utilized for said mechanism is the ability of "Nitinol" to return to a preformed shape after said methods of heating. This first characteristic gives the opportunity to incorporate an on/off mechanism into the general design, or an at rest and contracted state utilized in said mechanism. The said first ability of nitinol to contract 6-10% of its overall length while heated, is applicable to an on/ off mechanism or an extended/retracted form, with the application of an extension spring. Mainly after the heating process and when the Nitinol cools, the extension spring would "stretch" the nitinol to its original elongated shape. The second characteristic of nitinol to return to a preformed shape is applicable to the said mechanism of activation with an operator permanently activating the assembly, to have the preformed wire move from a deformed shape to its original deformed shape. In this said application the nitinol would return to a preformed elongated form, thereby linearly extending the said blunting/sheathing mechanism in order to cover and or guard the sharp point of the said needle embodiment. The said contraction of this assembly through ohmic heating would be conducted by the administration of electrical current through the said needle

holder mechanism and its variations shown in figure 2. Mainly the needle holder has two tips, one would be routed and insulated as the positive terminal and one would be routed and insulated as the negative, so that it would make corresponding contact to a positive side of the needle and a negative side of the needle, which in turn is connected to the said mechanism of activation, and transmits the electrical current to the nitionl giving the desired characteristic of contraction or shape memory return.

The assembly is designed to prevent the unwanted puncture or penetration of tissue, and or material within a sterile surgical field. However this method of linear projection of a blunting tip is not confined to the surgical field but could be used in other applications. The main principle is to prevent the transmission of body fluid borne pathogens from a patient to a person conducting a medical procedure, by the introduction of sheathing body to guard the sharp needle tip. The term sheathing body is widely used in this context however, some of the said embodiments for sharp point protection utilize a blunting effect, or a deflector type assembly to warn the operator of the said device and of the relation of the operator to the close proximity of the sharp point. Generally the force exerted during an accidental puncture is low, and is mainly due to snagging and "brushing" up against the sharp point. The deflector type design would generally be significant enough to prevent the occurrence of an accidental puncture, by deflecting the said sharp point.

The needle body shown throughout is of the general existing round variety of a suture needle. The said concepts could be applied to any shape of needle, with any tip variety with small modifications of the basic shape and design of the said sheathing mechanisms and mechanism of activation. These concepts could also be applied to other assemblies requiring minute linear extension for precision processes or sharp point protection, such as with Trocars, Razors, hypodermic needles, and the like. Figure 1 shows a general needle body, with an inner cannula 1D, an outer main body 1C, a needle tip 1A, and existing suture material 1B. Figure 1I is used to denote the sheath blunting or projection of an assembly, and signifies in figures 9B and 9D the said blunting effect and location of a general sheath for sharp point protection.

Figure 1J represents the cold phase of the shape memory alloy. Figure 1K represents the application of electricity to the said mechanism of activation. Figure 1L represents the application of heat to the said mechanism of activation, through represented means.

The sheath extension mechanism is activated by the said means of heating and there exists a variety of means to heat the mechanism, depending on the characteristics of the mechanism desired, and the relative ability and cost effectiveness of producing such an assembly.

Also, the current invention is not limited to Nitinol, as the sole material for the actual activation of the said assembly. With the continuing advent of micro-pizeo electric actuators, electro active polymers, micro-pistons, and other means of micro-linear activation, the mechanism of activation could incorporate any of these means as the technology becomes available in order to activate or project the said sheathing bodies, and replace the present idea of a Nitinol activated assembly.

Objects and advantages:

Accordingly besides the objects and advantages of the previously stated, several present objects and advantages of the present invention are:

(a) to provide multiple ways to construct a sheathing assembly depending on manufacturing techniques and possibilities, and consumer needs and preferences.

(b) to provide multiple shown ways for constructing a mechanism of activation.

(c) to provide 2 general forms for the sheathing/blunting assembly to act in a protective manner. **(I define "armed" as generally meaning the sharp point is exposed and readily available to carry out its penetration of tissue function, either permanently or temporarily. I define "disarmed" by the sharp point being sheathed or blunted by said mechanisms of sheathing/ blunting, either permanently or temporarily.)*

(1) to arrive safely *disarmed to the consumer, and have the capacity to be *armed and with the said on/off characteristics.

(2) to arrive to the consumer *armed, until the point where the operator

of the said device chooses to disarm* the needle embodiment, rendering it "safe" from that time forward.

(e) to provide multiple shown ways to construct the needle embodiment according to manufacturing means, processes, materials, methods, and consumer preferences.

(f) to provide multiple ways for activating the said needle body safety suture mechanism.

Summary:

In accordance with the present invention, a general suture needle assembly has a linear hollow shaft running the length of the needle body to the desired characteristics, the needle tip itself is constructed to accept the said sheathing/blunting mechanism, the needle body itself, is designed to allow the application or insertion of the said mechanism of activation, the mechanism of activation is deigned according to the desired said possible functions. The methods of activation for the said linear projection assembly, consist of two options, ohmic heating, and thermal heating depending on which mechanism is deemed more appropriate for the present invention.

The attachment and assembly and construction of all parts, would utilize well known and commonly used means, except where specified. For example, welding, crimping, gluing, joining, grinding, drilling, laser cutting, forging, photoelectric construction, and other widely known and other commonly accepted means. In the particular exception of ohmic heating in relation to the needle body for the said properties, the needle body would be designed and constructed as to allow the free transmission of electricity to the mechanism of activation, and would be constructed of materials as to allow the mechanism to be electrically insulated. The said power source located within or externally from the said needle holder options, would contain a pulse width modulation circuit, or some other form of electrical control to regulate the amount of current as to conserve power consumption and also prevent overheating of the SMA assembly.

Detailed description, explanation, and variations:

The accompanying drawings illustrate the variety of the needle embodiments, the said SMA mechanism of activation, the mechanism for activating the said SMA assembly, either in the

form of an attachment for an existing needle holder, or in the form of an entirely redesigned needle holder with said properties in order to activate the SMA assembly. Also other modes of activation are included, taking advantage of the properties of the said SMA material. The drawings also illustrate various configurations of the parts in general necessary to construct the SMA mechanism, according to manufacturing possibilities, standardized regulations on durability, and consumer preference. Multiple possibilities and varieties of construction for the said SMA mechanism of activation are also illustrated, and may be utilized depending on manufacturing constraints. The said SMA mechanism of activation, as previously stated also has two options which pertain to the method of construction. Namely if the needle is to have on/off characteristics previously described, it will need to incorporate a spring assembly, which I describe in the drawings as a normal extension spring constructed of any applicable and acceptable medical grade metal alloy. However, the spring itself is not confined to a metal spring configuration, but could be constructed of a polymer material, or configured by many other widely accepted means of placing a rebound tension on the mechanism itself. If the needle does not have on/off characteristics, but namely has the one time activation characteristic, a spring assembly is not needed, and the mechanism relies solely on the properties of the SMA material to return to its preformed shape in order to exert the linear extension of the sheathing assembly over the needle body.

There exists however an exception to this idea, in that a short amount of retraction may be desired to secure the tip firmly within a resting point, or a sheathing guard point within the sheath itself, as to entirely secure and encompass the sharp point of the needle. If this short amount of retraction is desired to accomplish the said affect, a small compression spring may be internally attached to the sheathing assembly or the mechanism of activation itself, in order to provide the minute retraction desired for the said behavior. The needle body itself is represented as being a suitable metal alloy of acceptable standards, however due to the nature of the mechanism in that it may need to be insulated from the electrical current which passes through it, high density polymers may be used to construct the outer needle body, or any of the other said

parts, depending on manufacturing tolerances and the design deemed as most desirable. The general representation of the entire needle assembly in these figures as shown as a hollow casing, with all other said parts resting inside this casing, with the remaining outer parts being constructed around the inner parts in a method of allowing the electrical current to flow through efficiently, allowing the process of ohmic heating, or thermal heating by thermal conduction. However, the present idea is not limited to the internal placement of any of the said parts. Any of the design or variations on any part of the assembly may be constructed and assembled at different points about the body of the needle assembly. Namely, it is possible to have the extension sheath externally located, and also it is possible to design the mechanism of activation as an external attached body separate from the main needle body itself, for example the SMA mechanism could run proximal to the suture material, distally from the tip of the needle.
The sheathing mechanisms shown give a general idea of how to accomplish the sheathing/blunting effect desired however, the mode of sheathing and blunting could also be carried out in other methods, for example, using an externally placed SMA wire that runs along the top side of the needle assembly that, when heated returns to a performed shape that would move over and cover the sharp point of the needle tip.

Fig. 1

Figure 1 is a general figure which represents the general needle body chosen to represent the said assembly. The shown needle shape is divided into 3 sections, the distal needle tip area in general represented by figures 3-8, and each figure of the grouping 3-8 provides specific detail on a variety of possible sheathing/blunting assemblies. It is inferred but not shown in all diagrams that there is a linear extension shaft that runs to some varying extent within the cannula of the said needle body, which connects the said sheathing assembly to the said mechanism of activation. In some representations of the present invention, the sheathing body would be designed so as to be part of the extension shaft itself. The shown needle shape of fig.1 is further divided into what is represented as the middle section for clarity, and is detailed in figures 9-10 as the mechanism of activation with the previously stated characteristics. The

location of this representation, does not limit the location of this said assembly specifically to this location, but allows for clarity in representing a linear functional assembly.

The last subdivision of the general needle figure, is the proximal end of the embodiment in reference to the suture material, and is detailed in figure 11. generally these figures show some of the ways to construct the external needle casing, and attach the suture material to the needle body itself, the construction of the said embodiment is general for clarity, and the parts detailed may be constructed, joined, and manufactured to other commonly known practices. The four figures grouped together as 1I-1k, are presented throughout the drawings to clarify the functional characteristics of the mechanism of activation in relation to the assembly and whether or not it is activated by heat 1J, activated by electricity 1K, or wither it is at rest with no heat or electrical energy being exerted upon it. The figure 1I refers generally to the presence of blunting mechanism, and is shown randomly throughout the drawings to reference the presence and or location of the blunting/sheathing assembly.

Figures 1E-1H show the general idea of the benefit of the said needle assembly. 1E represents the passing of the general device (figure 8 tip representation shown solely for example), between two persons and is intended to imply the behavior of the blunted characteristic of the figure 8 variation. Figure F shows the common practice of loading the said assembly by the operator onto the non-existing needle holder explained in figures 2.1, and again shows the blunting characteristic of this specific example. Fig. 1G shows the common practice of tissue penetration or suturing with the said "activated" blunting assembly of the fig. 8 variation of the said assembly, in particular activation is achieved by the depression of the activation button which is explained in figures 2. Fig. 1H shows the release of the said activation button, and as a result the deactivation, or disarming of the said assembly renders it less likely to result in an accidental puncture.

Fig. 2

Figure 2 shows a general widely used needle holder of any size. Figure 2A and 2B shows a described view of an attachment that has the purpose of carrying out the said function of

activating the suture needle mechanism by the application of heat or electricity. The said assembly for attachment to an existing needle holder, FIG. 2C-2E, has a vertical top portion 2P and a vertically corresponding bottom portion 2Q The two portions come together shown in figures 2F-2H, in an aligned fashion. This mechanism is designed so as to fit any variety of size of needle holders by utilizing this said idea with attachment points 2Y, which would fit over the corresponding portion of a needle holder, the said assemblies tow halves 2P and 2Q would join together with a tightening ratcheting mechanism 2X, consisting of a top portion 2Z on 2P that is notched for accepting the corresponding crew mechanism 2AA that is fixated within 2Q. The assembly would ratchet together 2F-2H, by the tightening of the fixed assembly 2AA which has a shaft that is adjustable by the insertion of a standard or Alan wrench. The tip portion 2R of the said 2P half, would be hollow in nature, as to allow the insertion of the corresponding needle holder tip sequence shown in 2I-2N. The assembly designed in the said way, would lock on to the existing needle holder by tightening the said ratcheting mechanism, and could fit a variety of different sized needle holders if necessary. The secondary tip appendage of the said attachment, would also be hollow in nature, and fit over the second needle tip holder portion or "jaw" sequence shown in 2L-2N. It would be retained by a screw mechanism 2M that would tighten down onto the second needle holed trip 2BB, or screw directly into a hole 2O that could be placed within the needle holder tip 2BB. The secondary tip of the said assembly would be connected to the main upper body of the assembly 2P, by a small wire 2U, or mechanism which would allow for the insulated transmission of the needed electrical current to the conductive surface 2V. Explained simply, the attachment, would have two corresponding tips 2R and 2P tip portion, that would fit over the needle holder tips 2W and 2BB, and provide a conductive surface 2V for the transmission of electricity to the said needle body, or have internally located heating elements 2.2 that would provide the needed heat for the said needle body mechanism of activation. The said attachment, would have an internal power supply 2U, and a simple internal circuit and circuitry (not shown). Both the power supply and the circuit (not shown) could be located off of the unit 2.2C and be located at a fixed point in a different power supply unit 2.2D

with controls 2.2E, a cord 2.2G that connects to the needle holder, and an attachment plug 2.2F, that corresponds to the cord. The circuit is a simple circuit of the pulse width modulation variety, or any other variety as to control the nominal amount of voltage required, as to prevent the overheating or malfunction of the assembly of activation. The circuit would have a switch or button 2S, that would be correctly and anatomically located as to allow easy activation by the operator in order to activate the said mechanism of activation.

In particular, the said attachment to the needle holder, could be constructed as one piece and fulfill all said characteristics by incorporating the needed assemblies into one needle holder r mechanism fig. 2.1 and 2.1A. Also, other methods of activation exist but are not limited to the following, a warm container of water 2.2B, a hot plate 2.2A with an internal or external power supply (not shown), circuit (not shown), and heating element (not shown). Any configuration of the above assemblies used in conjunction with the mechanism of action of the needle itself, could be used.

Fig. 9

In order to better explain the said properties of the mechanism of activation, I present figures 9A-9Q. The figures within 9A represent the characteristic of the SMA to be at rest with any preformed shape; in this specific example, a coil. During a heat annealing process the alloy is raised to a temperature above its transition point, and then deformed at that point. Upon cooling, the alloy is then deformed again to the desired shape. When the alloy is heated by said means at a later time, it has the special property to return to its previous set shape that was formed during the annealing process. Figure 9O then shows the linear movement desired of the mechanism of activation with the application of heat or electricity to the material. The vertical column within the brackets of 9G represents the length of the horizontal placed material. The vertical column of Figure 9F represents the distance that the blunting mechanism and or extension assembly has to travel to reach the point at which it acts as a blunting/sheathing mechanism. The vertical column of 9E represents the area at which the sheathing/blunting mechanism is acting with its said purpose. 9B represents a general needle shape in reference

to its blunting/sheathing assembly and the characteristics of the said assembly defined in 9A and the location of the said blunting sheathing assembly. Fig. 9P at rest and Fig. 9Q when activated and the intended direction of travel.

Figure 9C shows the properties of the said mechanism, with the extension spring for linear extension. Fig. 9H represents the said assembly, at rest with the SMA material at the inner core of the assembly. Fig. 9L. shows the retraction of the SMA material, which ranges from 6%-10% of its overall length when the said forms of energy are applied to it. The SMA material contracts and the diameter increases in a corresponding range. This fact is taken into consideration when constructing and inserting the needle assembly into the said needle embodiment. Fig. 9J shows the extension of the SMA material by the force exerted upon it by the said extension spring. Again, the vertical column within the brackets of 9G represents the length of the horizontal placed material . Again, the vertical column of Figure 9F represents the distance that the blunting mechanism and or extension assembly has to travel to reach the point at which it acts as a blunting/sheathing mechanism. Again, the vertical column of 9E represents the area at which the sheathing/blunting mechanism is acting with its said purpose.

The figure 9D represents a general needle shape in reference to its blunting/sheathing assembly and the characteristics of the said assembly defined in 9C, and how the blunting/sheathing assemblies location is affected in each process. Fig. 9K shows the sheath at rest, Fig. 9L shows the sheath being retracted, figure 9M shows the sheath being extended by the said extension spring.

Fig. 3

A general round suture needle is presented in Fig. 3 and shows a radial sheath assembly 3Q protruding distally from the needle, rendering the sharp point covered as to protect the operator. Fig. 3A shows the same general needle with 3Q at its retracted position. Fig, 3A-3I show specific defined views and the relation of the said parts to the assembly. The said sheath has a vertical channel 3J which allows for the expansion 3P of the sheath in order to slide over the needle tip upon retraction or extension Fig. 3I. 3Q comes to rest within the space 3R which is

formed from the main needle body and the channel meets the elevated ridge 3O which is formed from the main needle body, in order to secure the sheath during its various said sequences. The sheath 3Q is attached or is itself part of an extension 3K, which runs through an aperture 3N within the needle body itself 1C to the inner cannula 1D where it is attached to the said mechanism of activation Fig(s) 10. 3Q has a slightly rounded edge on the superior portion 3L, as to prevent the formation of an additional puncture hazard, and to also allow for easy passage from 3R to its extended position. The front side of 3R near the raised ridge 3O is made smooth (not shown) for an easy transition of 3Q to move freely from the extended to the retracted position. The sheath is stopped and makes a tight junction upon meeting 3M which is a resting uniform ledge. The sheath assembly could be modified to fit any tip size shape or characteristic desired.

Fig. 4

A general round suture needle is presented in Fig. 4 and shows a sheath assembly 4V protruding distally from the needle, rendering the sharp point covered as to protect the operator. Fig. 4A shows the same general needle with 4V at its retracted position. Fig, 4B-4E show specific defined views of the assembly and the relation of the said parts to the assembly and needle tip 1A. The said shield like sheath 4V has a point on the bottom of the sheath so that when the shield moves over the needle tip when used in the context of one time activation with a said small retraction spring fig.10H mechanism within the said assembly of the mechanism of action fig. 10, the needle tip comes to reside within a sharp tip catching point fig. 4X which "locks" the said shield on to the needle tip 1A. The said shield is blunted or slightly rounded fig. 4Y about its outer perimeter, as to not produce an additional sharp area. The shield is then connected to an extension 4W or is uniformly constructed as part of the extension itself. The extension 4W is then connected to the mechanism of action itself fig(s) 10. The shield upon retraction comes to reside within an aperture of the main needle body fig. 4U. Upon retraction the said shield and needle body 1C form a radial uniform body, so that there is no catching or unwanted drag from the needle during passage through tissue. Figure 4F shows a side view of

the aperature in relation to the needle body. The shielding mechanism and aperture are located close enough to the tip 1A so as to equate the amount of travel given from the extension and contraction of the assembly of activation, and also so that the tip is not weakened by the aperture being placed to close to the narrowest portion of the needle tip, which could possibly weaken the tip and needle body. In order to guide the shield to its proper orientation upon retraction and or extension a groove (not shown) could be placed within the needle body distal to the aperture that would match the said extension shaft, so that when the mechanism is in movement, the groove the shield would orient into its proper alignment. Figures 4G-4I show in detail the shielding mechanism and extension shaft. The extension shaft 4W has one or more "catch points" fig. 4Z to reduce flexion of the shield if force is applied to the shield that may displace the shield out of its protective function. The catch points are accepted by grooves within the needle body 4AA, as to capture the sheath so it performs the said function in a secure manner. Figure 4T gives a detailed explanation of the said resting points 4Z in relation to the catch point grooves 4AAThe shield could be formed so that no sharp tip catch point exists, and the needle could be activated and deactivated multiple times by the retraction and extension of the said assembly shown in figures 4J-4S. The sheath assembly could be modified to fit any tip size shape or characteristic desired.

Fig. 5

A general round suture needle is presented in Fig. 5 and shows a preformed wire like assembly 5N protruding distally from the top medial portion of the needle tip 1A, through two exit apertures 5L and 5M. Fig 5A shows the same tip concept with the blunting mechanism at rest, or retracted into the main needle body. The blunting wire mechanism could exit as a sole unit from the said main body extension shaft through the secondary drilled aperture 5O, as two separate but joined wires to the main extension shaft, or could also have plate covering the aperture 5J, that could have one hole or possibly two holes 5L and 5M depending on the formation of the preformed wire assembly 5N. Any variation of exit for this type of blunting mechanism in the positioning of the wires, is only limited to the most efficient manufacturing design. Fig. 5I shows a

transparent lateral view of a secondary aperture 5O that could be positioned at any angle to form the most efficient and correct angle for exit of the blunting assembly. The blunting mechanism located within the shown area would retract when activated to the accepting groove 5K, and would rest at this location. The blunting assembly 5N would have a characteristic shown in fig. 5H of lateral flexibility, while moving over the needle tip point, in order for a tight joining of the wire and the needle body itself 1A. Fig. H, demonstrates the said lateral flexibility of the wire loop, and figure 5G shows the uniform nature of the wire, rested within the accepting channel 5K upon rest. The wire would be constructed of existing means, and have a full circle diameter shape fig. 5F except for the portions that would come to rest within the groove which would be of a half circle shape fig. 5F, or of any shape necessary to create a uniform exterior so as to reduce snagging of the wire fig. 5G. Fig, 5B-5E show specific defined views of the assembly and the relation of the said parts to the assembly and needle tip 1A.

Fig. 6

A general round suture needle is presented in Fig. 6 with a blunted wire 6R that projects from the tip 1A upon extension, the exit of the blunted tip itself would be linear to the sharp point tip as to provide a blunting body that a surface would come into contact with primarily as opposed to the sharp tip of the needle. Fig 6A shows the blunted wire projection retracted, and the tip itself, is blunted just enough 6S so as to not act as another sharp area. fig. 6R, but not be blunted to the extent as to allow snagging of the tissue upon desired penetration. The blunted extension, could be one unit that connects to the said mechanism of activation assembly fig. 10, or could be an additional lateral extension 6T, that connects to a general extension from fig. 10. Specific views are detailed in fig(s) 6B-6E, and 6G-6H of the said assembly and details. A variation could exist shown in fig. 6G where the blunted tip itself could have a preformed curving nature to it fig. 6Q, so that when 6R extends the said projection would have a spring like characteristic to point over the needle tip. Upon retraction, the spring like bending effect would be small enough, as to facilitate easy retraction, and the curved assembly would straighten and fit snuggly into the main lateral cannula 1D. Also, if this tip was to be used with the said, one

time activation properties, the blunted projection wire, could have within it, a resting catch point groove shown in figures 6M and 6N. This catch point would serve as a "lock" for the projection, and could be combined with the said small retraction mechanism () in order to fit the projection snuggly on to the tip. A second aperture 6O could be formed, shown in fig. 6F, and positioned at any feasible location as to allow the most efficient exit angle for the said projection wire. Figures 6I-6L, show specific views of this assembly with detail. Also, it is a consideration to have a wire extension fixed at a point proximal to 1A, but free to move vertically upon extension of the said mechanism, and also distally to cover the needle tip and provide a blunting effect. Fig. 6P shows this idea, but is not expanded into detail only stating the general idea, combining the said properties and variation of this design.

Fig. 7

A general round suture needle is presented in Fig. 7 with a projection wire 7R which has two ends, with one end being fixated at some point either proximal and equal to each other 7N or laterally and distal to each other 7,7A-7J. In the first variation both ends of the wire loop projection are attached at the same point fig. 7N, which is either the main general extension shaft, or directly connects to the mechanism of activation at a defined point 7T. The two separate ends of the extension could also be placed laterally opposite of each other, with separate exit holes 7Q, that are uniform with the main lateral cannula 1D. Fig. 7M shows a close up view of this concept. In the second variaiton the said projection wire 7R is fixated at the point of attachment to either a general main extension or the mechanism of activation itself at its proximal end, and then at a lateral fixation point located on the needle body itself fig. 7O.. This concept would allow for the wire to expand laterally and then distally, and could have a perfumed general curve shape that would extend in a manner as to provide the necessary blunting effect. For both variations, the wire is of a shape so as to correspond to a tight fitting resting point 7P when retracted to the main needle body, similar to the previously said concepts of figures 5. Fig. 7L once again shows this concept of a wire being shaped in diameter to correspond to the needle body and resting groove 7P. The exact placement of the exit guide channel 7S would

depend on the most efficient angle and method of manufacturing. Similar to the concepts within figures 5 a secondary guide channel with a plate covering and corresponding holes for the wire projection for the wires to exit, could exist. Figures 7, 7-K, showed detail views of the said assembly.

Fig. 8

A general round suture needle is presented in Fig. 8, with a break away tip design upon extension of the said mechanism of activation. The idea is that when the needle tip 8L is inactivated, it is suspended from the needle body 1C by a flexible extension material 8J, and is freely able to move. The distal tip of the needle body when the needle tip is suspended is blunted 8M as to not provide a secondary sharp surface. Upon the retraction of the mechanism of activation the needle tip would retract, being guided by a simple ridge and groove assembly (not shown) or particular strengthen(not shown) of one side of the flexible extension 1J, or by some other property that would clearly guide the needle tip to the main needle body. The mechanism of activation would tightly secure the needle, so that any normal force exerted upon it during penetration would keep the needle tip aligned in its proper arrangement. Fig. 8D shows the flexible properties of this extension, and is drawn to illustrate the break away, or hanging to the side fig. 8H of the mechanism property. The connection 8K between the flexible extension, and the main general extension fig. 8G could be constructed using any normal means and also the connection between the needle point 8L and the flexible member extension 8I. Figures 8A-8F illustrate the said assembly with said stated views.

Fig. 10

Figure 10 in shows a general idea of the parts required as said, for the construction of the current invention and all of its possible variations. The construction of the current invention is not limited to these parts specifically, but is intended to give a general idea of the mechanism of activation in its said forms, and the properties needed to accomplish such a function and the required general materials. Fig. 10A represents the shape memory alloy, namely Nitinol, and all its possible variations, taking advantage of its said properties. If the nitinol assembly is to

achieve the desired contraction effect by ohmic heating, it must have a positive and negative terminal end for the conduction of the electrical current, and be electrically insulated in various aspects by traditional means. The transmission of the electrical current can be achieve through various means, but is generally represented by the figure 10F, that is a conducting wire. However the spring assembly itself could act as a conductor, the nitinol could be filled with a conductive matrix, or the wire could be routed through the nitinol, or the distal end of slider point attached to the nitinol could make contact with the positive side of the needle and the negative side. and any combination of the body itself and or these parts or others could help achieve the proper conduction of the SMA material for said properties. The contact points for the said conduction possibilities ultimately need to be routed to the needle holder itself, for the property of ohmuc heating. Therefore, a point namely 10B is needed to be placed in contact with the external contact point of the needle body, and a corresponding point, 10D to complete the path. For simplicity of the design, and due to the relative amount of the size constraints, the assembly needs to take advantage of as few parts as possible. Therefore, the main body construction is formed so as to give separate conduction areas, namely positive and negative sides. I refer to these sides as plates, and can be actual separate pieces of the needle body The said spring form 10C and all of its variations is constructed to the specification and retained so as to provide the proper amount of exertion upon the spring so as to extend the SMA material after contraction, but still be able to be overcome by the contraction of the SMA material. Also a spring 10H could be used in the assembly to achieve the said one time activation, for the sharp tip nesting point mechanism. Namely that when the whole assembly is ac invited and the linear projection in its said forms is extended, the short retraction spring, would contract the mechanism just enough so as to allow the resting point to arrive at its desired location, and provide a snug fit. A main extension shaft 10E is connected to the sheathing/ blunting assemblies, and is then connected to the distal contact point of the SMA assembly, or to a slider mechanism that could freely move within the needle body cannula 1C, and could even act as one of the conduction points in relation to moving within and making contact with the main needle body conduction

parts.

Variations to the one time use mechanism, pertain to the said property of nitinol to contract when heated. The following concepts could be applied by any methods of heating either stated or unseen. Fig. 10.1A embodies 10.1AA-AD, and is shown as a mechanism that is generally shown to have a SMA wire 10A, that has a crossbar 10.1AE of bendable material that is either part of or separate to an extendable retention plate 10.1AG that is acting as a retaining device for an extension spring 10.1A. The crossbar assembly and retention plate form a unit that retain the spring from extending. The SMA wire, is looped over the crossbar, so that when the SMA wire is contracted by said means, it pulls the crossbar down, or breaks it free from its contact points 10.1AF with the slider, pulling the crossbar down through an opening in the slider 10.1AH, and releasing the tension of the spring 10.1AI which in turn is driven to extend linearly the extension plate which is in some form connected to the sheathing mechanism. Figures 10.1B, and 10.1C denote a similar mechanism compromised of the same parts in 10.1D-E that is under tension, but the nitinol is attached to the slider plate by a crimped or locked in place area 10.1BD. Figures 10.1C-CF, also show a similar variation of this under tension mechanism, however the SMA is glued to the extension plate 10.1CD, and the bond strength is sufficient enough to retain the spring, yet break when the SMA contracts. Figures 10.1D-I, describe a similar mechanism that is under tension, however the nitinol has slider plate with a groove 10.1DG, that the SMA extends through, and the SMA has an attached retention point 10.1DE, that rests firmly in slot 10.DF. When the SMA contracts, it "pops", the retention point from its resting spot, and slips it through the corresponding groove within the slider plate, thereby releasing the plate which is under tension form the said spring, which extends the slider plate which is connected to the extension or sheathing/blunting assembly. Figures 10.1E- EC. show another variation on this concept, but a slight bend in the SMA acts as the retaining area of the mechanism, which is holding the extension spring under tension, When the SMA contracts, it releases the said spring, linearly extending the sheathing mechanism as previously stated. Figures 10.F-FI, show a similar assembly under tension, however there is an actual SMA plate

10.1FE that is preformed in a bent fashion , with a hole that is deformed 10.1FF at its bended state in order to retain an extension shaft that has a retained point 10.1FG, that is unable to slide through the hole 10.1FF, until the said SMA plate is contracted, opening up the joint allowing the retained point 10.1FG to slide through thereby releasing the tension bound spring, which is connected to the said linear extension assembly.

The most simple design, and the idea that eliminates all of these small intricately engineered parts, is the concept of one time activation, pertaining to the linear extension of a deformed nitinol wire, that would be activated by external means, all of these mechanisms could be applied however, a lone deformed SMA shape, which would extend linearly thereby extending a sheathing mechanism, or act as a sheathing mechanism itself is the most efficient. Figures 10I-L show the general relations of the assemblies of activation in relation to the external needle body parts and the general fixation of all said parts, but is not limited to these areas, or sequences of parts placement and or general assembly.

Fig. 11

All of the figures in group eleven clearly denote the various assembly and construction of the needle body in order for the needle body to conduct electricity, be structurally sound, and be able to retain the said internal mechanisms. The current embodiment is not limited to these construction principles, but is open to design variation, in order to accomplish these said objectives.

Fig. 11 denotes a the general suture needle, in its curved form. The exterior main needle body, is manufactured according to current known means. The Main needle body and its accessories would be formed separately form the top conduction plate 11N and bottom conduction plate 11O in this example. The needle body would be formed by said existing means, as to retain two proximal side portions that both would run laterally half the length of the needle. The needle body would have a core section removed, leaving two side walls 11P and 11Q in order to make space available for the said conduction plates, and provide an area for attachment of the said conduction plates. The side panels, and the conduction plates would be

joined using existing means, and are insulated with current technology such as Teflon coating, of other standard means. The said parts as whole, form the exterior needle body as a whole giving it the property of having an internal hollow cannula 1D. On either of the plates, there could exist a portion, that would act as a conduction point, and or an attachment abutment for the suture material figure 11R. These separate parts, would be made and connected so as to provide a proper conduction pathway to transmit the necessary electrical current, or act as a retainer for any of the variety of the said mechanism of activation. Figure 11 A, and 11AA show described views of this assembly concept. Figure 11B shows a similar main needle body design, but only having a top plate for conduction of one the terminal ends, and the main needle body which could act as a conduction plate itself for the either terminal end of the circuit. figures 11C and 11CA show described views of this assembly concept. Figure 11D illustrates the said main needle body, being constructed of 3 separate pieces. A top plate 11N, a bottom plate 11O and the main needle distal needle body 1C. The pieces would form a whole, with the said characteristics. Figures 11E and 11EA show described views of this concept. Figure 11 G shows a simple illustration, of a needle body, being constructed of only one piece, in general, that would be sufficient to accept some of the said mechanisms of activation. In particular this design would be most suitable for the said 1 time use mechanism stylizing the shape characteristic of the SMA material. Figure 11F shows a two piece design of a top plate that runs the length of the needle body, and a bottom plate which fully corresponds to the top plate in order to achieve the said characteristics. The joining of all these parts, is open to existing means, using adhesives, crimping, welding, and also the utilization of new means according to this context. Figure 11L gives a close up, of ridges or teeth 11V that would run along the underside of the top and bottom plates, in order to give a grasping surface to retain the said suture material. Figure 11I shows a close up cutaway view of this potion of the needle in relation to the bottom and top plates the conduction and attachment point 11R and the other said pieces. Figure 11Figure 11H shows the possibility of utilizing a ring type fixture to encompass the said parts of the needle assembly, and could be used to retain all of the pieces as one, either e by

crimping this said ring fixture 11T, or by traditional means, such as gluing, welding etc.. The corresponding portions 11U of the needle body parts would be manufactured to accompany the ring, as to not provide any surface that would cause snagging, or other unwanted effect. Figure 11J shows a general figure with the suture in place to the said needle parts. Figure 11M illustrates the concept of channeling and notching the corresponding portions of the needle body in order to assembly the said parts. figure 11K illustrates the known concept of crimping the needles proximal end, in order for suture material retention, and could be used to join all of the said parts in some fashion Once again, the overall assembling of the exterior needle body is open to any traditional means, but consideration to the construction must be given in order for the characteristics of strength, conductivity, insulative properties, mechanism retention, and needle body construction. Once again any material could be used to construct these parts, in particular any high grade strength steel, or polycarbonate material. an also any means of joining these parts, that is considered acceptable, such as a high strength adhesive, or micro welding of the said parts.

Figure descripti ns.
(8 pages)

Figure

1A- Needle Tip (sharp point).
1B- Existing Suture Material.
1C- Needle Body.
1D- Main Lateral Cannula (Hollowed out bore).
1E- Figure representing the passing of said needle between two persons.
1F- Figure representing the loading of said needle onto a needle holder.
1G- Penetration of said needle through tissue.
1H- Disarming of said needle.
1I- Indicates location of general blunting mechanism during stages of activation sequence.
1J- Represents the inactive state of said mechanism.
1K- Application of electrical current for activation of said mechanism.
1L- Application of heat for activation of said mechanism.

Figure

2- Existing needle holder.
2A- Right side view of said assembly to needle holder.
2B- Left side view of said assembly to needle holder.
2C- Right side view of said assembly.
2D- Left side view of said assembly.
2E- Top view of assembly, with secondary attachment appendage shown in top view.
2F- Superior and inferior sections aligned for assembly.
2G- Insertion of the two sections.
2H- Joining of the two sections.
2I- Attachment sequence of the needle holder tip and secondary tip attachment.
2J- Aligned sections.
2K- Secondary tip appendage aligned with needle holder tip, beginning of attachment.
2L- Secondary tip appendage secured.
2M- Secondary tip attachment mechanism.
2N- Secondary tip attachment bolt.
2O- Modified secondary tip predrilled hole.
2P- Upper section of said assembly.
2Q- Lower section of said assembly.
2R- Secondary tip appendage.
2S- Activation switch.
2T- Wire connector to secondary tip from main assembly body.
2U- Battery power supply.
2V- Conductive surface.
2W- Primary needle holder tip.
2X- Ridge showing the elevated tensioning mechanism area.
2Y- Ridge and groove for assembly retention on needle holder.
2Z- Top horizontally grooved rail for tensioning mechanism.
2AA- Fixated tensioning assembly.
2BB- Needle holder secondary tip.
2.1- Lateral view of said nonexistent needle holder.

2.1A- Left side view of said nonexistent needle holder.

2.2- Cutaway view of said non existing needle holder with heating element in the tip for said means of activation (heating element not shown).
2.2B- View of a nonspecific container of hot water.
2.2A- View of a nonspecific hot plate with either internal or external power supply, and Internal heating element.
2.2C- Said nonexistent needle holder with off unit power supply.
2.2D- External power supply unit.
2.2E- Power supply controls.
2.2F- Plug connector for power supply and said needle holder.
2.2G- Power cord.

Figure
3- Solid left perspective view, of general suture needle and inactive protective sheathing body tip variation.
3A- Solid left perspective view, of general suture needle and activated protective sheathing body.
3B- Solid Front orthogonal view of active sheathing body and needle tip.
3C- Transparent front orthogonal cutaway view of inactive sheathing body and needle tip.
3D- Solid rear orthogonal view of activated sheathing body and needle tip.
3E- Solid front orthogonal view of inactivated sheathing body and needle tip.
3F- Cross sectional view of needle holder tip point appendage.
3G- Solid front view of activated needle tip, showing resting sheath in relation to guide channel and guide ridge.
3H- Exploded isometric view of actual sheath .
3I- Representing 3 segments of sheath retraction, and extension in the reverse process.
3J- Vertical expansion groove within sheath.
3K- Raised attachment portion of main stem portion, to sheath body.
3L- Figure showing the slightly blunted and rounded edges of the sheath body.
3M- Resting ledge of main needle body, for resting sheath body, upon retraction.
3N- Vertical opening from main needle body for raised attachment of main stem.
3O- Lateral ridge guide, which accompanies the vertical channel located within the sheath body.
3P- Expanding sheath body, sliding over the needle tip.
3Q- Sheath assembly.
3R- Sheath retraction resting area.

Figure
4- Solid Left perspective view of general suture needle and inactivated shielding assembly.
4A- Solid Left perspective view of general suture needle and activated shielding assembly.
4B- Transparent front orthogonal view of general suture needle tip and inactivated shielding mechanism.
4C- Transparent front orthogonal view of general suture needle tip and activated shielding mechanism.
4D- Solid front orthogonal view of general suture needle tip and activated shielding mechanism.

4E- Solid front orthogonal view of general suture needle tip and inactivated shielding mechanism.
4F- Cutaway transparent side view of general suture needle tip body, and sheath resting point aperture.
4G- Solid top view of shielding assembly and cutaway extension shaft.
4H- Solid bottom view of shielding assembly and extension shaft.
4I- Left perspective view of shielding assembly.
4J- Solid Left perspective view of general suture needle and inactivated shielding - assembly, without said needle tip guard catch point.
4K- Solid Left perspective view of general suture needle and activated shielding assembly without said needle tip guard catch point.
4L- Transparent front orthogonal view of general suture needle tip and activated shielding mechanism without said needle tip guard catch point.
4M- Transparent front orthogonal view of general suture needle tip and activated shielding mechanism without said needle tip guard catch point.
4N- Solid front orthogonal view of general suture needle tip and activated shielding mechanism without said needle tip guard catch point.
4O- Solid front orthogonal view of general suture needle tip and inactivated shielding mechanism without said needle tip guard catch point.
4P- Cutaway side view of general suture needle tip body, and sheath resting point aperture without said needle tip guard catch point.
4Q- Solid top view of shielding assembly and cutaway extension shaft without said needle tip guard catch point.
4R- Solid bottom view of shielding assembly and extension shaft without said needle tip guard catch point.
4S- Left perspective view of shielding assembly without said needle tip catch point.
4T- Close-up left cutaway side view of resting point groove and extensions in relation to the needle body, and shown intended mechanism of action, and shield retention.
4U- Sheath resting point aperture on needle body.
4V- Sheath assembly in general.
4W- Sheath assembly extension shaft.
4X- Sharp needle tip guard catch point.
4Y- Slightly blunted edge of sheath.
4Z- Sheath resting point extensions.
4AA- Sheath resting point grooves.

Figure

5- Solid left perspective view, of general suture needle and inactivated protective sheathing loop tip variation.
5A- Solid left perspective view, of general suture needle and activated protective sheathing loop tip variation.
5B- Transparent front orthogonal view of cutaway activated loop variation.
5C- Transparent front orthogonal view of cutaway inactivated loop variation.
5D- Solid front orthogonal view of cutaway activated loop variation.
5E- Solid front orthogonal view of cutaway inactivated loop variation.
5F- Close up view of ½ circle wire variation drawn to normal round extrusion shape.
5G- Showing the resting of the protective wire body, within the nesting groove.
5H- Showing the flexible properties of sheathing assembly, for accommodating extension and contraction of sheathing mechanism, so that the protective loop

fits uniformly within the resting groove.

5I- Transparent lateral view of secondary guide channel variation.
5J- Secondary guide channel covering plate with secondary holes.
5K- Circumferential Nesting groove for accepting loop when activated.
5L- Left wire loop exit aperture for protective body extension.
5M- Right wire loop exit aperture for protective body extension.
5N- Preformed section of protective loop sheathing body.
5O- Secondary guide channel area.

Figure

6- Solid left perspective view, of general suture needle and inactivated protective blunted wire projection tip variation.
6A- Solid left perspective view, of general suture needle and activated protective blunted wire projection tip variation.
6B- Transparent front orthogonal view of activated blunted wire projection tip.
6C- Transparent front orthogonal view of inactivated blunted wire projection tip.
6D- Solid front orthogonal view of activated blunted wire projection tip.
6E- Solid front orthogonal view of inactivated blunted wire projection tip.
6F- Left cross sectional side orthogonal view of secondary guide channel variation.
6G- Solid left perspective view, of general suture needle and inactivated protective blunted wire projection tip, with preformed curve, and sharp point nesting area variation.
6H- Solid left perspective view, of general suture needle and activated protective blunted wire projection tip, with preformed curve, and sharp point nesting area variation.
6I- Transparent front orthogonal view of activated blunted wire projection tip.
6J- Transparent front orthogonal view of inactivated blunted wire projection tip, showing the sharp point nesting area.
6K- Solid front orthogonal view of activated blunted wire projection tip.
6L- Solid front orthogonal view of inactivated blunted wire projection tip.
6M- Transparent lateral orthogonal view of inactivated wire tip, and sharp point nesting area.
6N- Orthogonal close-up view of sharp tip nesting area.
6O- Secondary guide channel.
6P- Side view of fixed point extension wire in the extended position.
6Q- Blunted extension preformed curve.
6R- Blunted extension of main lateral extension wire.
6S- Blunted tip portion.
6T- Attached extension wire.

Figure

7- Solid left perspective view, of general suture needle and inactivated protective non-preformed wire loop projection variation.
7A- Solid left perspective view, of general suture needle and activated protective non-preformed wire loop projection variation.
7B- Transparent front orthogonal view of activated wire loop projection.
7C- Transparent front orthogonal view of inactivated wire loop projection.
7D- Solid front orthogonal view of activated wire loop projection.
7E- Solid front orthogonal view of activated wire loop projection.
7F- Solid left perspective view, of general suture needle and inactivated protective non-preformed wire projection, with permanent lateral fixation of distal wire

projection variation.

7G- Solid left perspective view, of general suture needle and activated protective non-preformed wire projection, with permanent lateral fixation of distal wire projection.

7H- Transparent front orthogonal view of activated wire projection, with permanent lateral fixation of distal wire projection.

7I- Transparent front orthogonal view of inactivated wire projection, with permanent lateral fixation of distal wire projection.

7J- Solid front orthogonal view of inactivated wire projection, with permanent lateral fixation of distal wire projection.

7K- Solid front orthogonal view of inactivated wire projection, with permanent lateral fixation of distal wire projection.

7L- Close up perspective view of projection wire loop.

7M- Cross-sectional side view of lateral secondary channel placement for wire location.

7N- Close-up view showing attachment to main slider or extension body.

7O- Lateral transparent close up view distal wire fixation point.

7P- Nesting channel for activated retracted projection wire.

7Q- Secondary Channels.

7R- Projection wire.

7S- Guide channel.

7T- Connection of projection loop to extension shaft or mechanism of action assembly.

Figure

8- Solid left perspective view, of general suture needle and inactivated protective Break away tip variation.

8A- Solid left perspective view, of general suture needle and activated protective Break away tip variation.

8B- Transparent front orthogonal view of activated break away tip.

8C- Transparent front orthogonal view of inactive break away tip.

8D- Transparent front silhouette view of extension and retraction sequence, of break away needle tip design.

8E- Solid front orthogonal view of activated break away tip.

8F- Solid front orthogonal view of inactivated break away tip.

8G- Close-up of main slider extension, direct SMA point, flexible member, and or other attachment configuration.

8H- Represents the break away, and intended free movement.

8I- Attachment point for flexible member extension within needle point.

8J- Flexible member extension.

8K- Flexible member attachment point to main slider extension.

8L- Break away tip main body.

8M- Blunted edge of main distal main needle body.

Figure

9- properties of Shape memory alloy in relation to needle mechanism.

9A- Showing the SMA mechanism at rest and then activation.

9B- Showing the shape memory effect of the said Shape Memory Alloy mechanism.

9C- Showing the activation and deactivation properties of the said SMA mechanism.

9D- Showing the relation of the said SMA mechanism in relation to the said activation of the said blunting mechanism.

9E- This vertical area denotes the location of the blunting mechanism either prior to or during activation of the particular said mechanism.
9F- This vertical area denotes the location of the blunting mechanism either prior to or during activation of the particular said mechanism.
9G- This vertical area shows the length of the said SMA mechanism relative to the spring extension and or contraction of said mechanism and its length during each said phase.
9H- *Inactive SMA with extension spring and said mechanism properties.*
9I- Activated SMA with extensions spring and said properties.
9J- Deactivated SMA with extension spring and said properties.
9K- Corresponds to 9H showing the relation of the mechanism to the blunted portion of the said mechanism in relation to a general suture needle shape.
9L- Corresponds to 9I showing the relation of the mechanism to the blunted portion of the said mechanism in relation to a general suture needle shape.
9M- Corresponds to 9J showing the relation of the mechanism to the blunted portion of the said mechanism in relation to a general suture needle shape.
9N- SMA at inactive deformed state.
9O- SMA returning to preformed state upon activation.
9P- Corresponds to 9N showing the relation of the mechanism to the blunted portion of the said mechanism in relation to a general suture needle shape.
9Q- Corresponds to 9N showing the relation of the mechanism to the blunted portion of the said mechanism in relation to a general suture needle shape.

Figure 10

10- Broad figure of parts.
10A- SMA with said variations and properties. (not all shown).
10B- Proximal end connection point with said variations and properties (not all shown).
10C- General extension spring (variaitons not shown).
10D- Denotes a connection point.
10E- Extension shaft with said variations (not all shown).
10F- *Conduction wire with said variations (not all shown).*
10G- Denoted insulating layer.
10H- Shirt retraction spring, with said variations (not all shown).
10I- Assembly in relation to needle body assembly (not all variations shown).
10J- Assembly in relation to needle body assembly (not all variations shown).
10K- Assembly in relation to needle body assembly (not all variations shown).
10L- SMA shape memory application assembly in relation to needle body assembly (not all variations shown).
10.1AA- Break away one time use mechanism, SMA loop with retention crossbar variety.
10.1AB- Side view, break away one time use mechanism, SMA loop with retention crossbar variety, inactivated view (spring not shown).
10.1AC- Break away one time use mechanism, SMA loop with retention crossbar variety, inactivated side view (spring not shown).
10.1AD- Break away one time use mechanism, SMA loop with retention crossbar variety, activated side view (spring shown extended & divided for clarity).
10.1AE- Crossbar.
10.1AF- Cross bar support.
10.1AG- Slider plate.
10.1AH- Crossbar aperture.

10.1AI- Extension spring.
10.1B- Break away one time use mechanism, SMA loop with crimped retention area.
10.1BA- Break away one time use crimped retention mechanism, inactivated.
10.1BB- Break away one time use crimped retention mechanism, side view, inactivated.
10.1BC- Break away one time use crimped retention mechanism, activated.
10.1BD- Crimping area.
10.1BE- Slider plate.
10.1C- Break away one time use mechanism with glued in SMA spring into retention area.
10.1CA- Break away one time use retention mechanism, with glued in SMA spring into retention area, inactivated.
10.1CB- Break away one time use retention mechanism, with glued in SMA spring into retention area, side view, inactivated.
10.1CC- Break away one time use retention mechanism, with glued in SMA spring into retention area, side view, activated.
10.1CD- Slider plate.
10.1CE- Retention area.
10.1CF- Focus of glued area.
10.1D- Break away one time use mechanism, with lateral SMA wire fixated with a vertical retention focus area to slider plate, inactivated.
10.1DA- Break away one time use mechanism, with lateral SMA wire fixated with a vertical retention focus area to slider plate, front view, inactivated.
10.1DB- Break away one time use mechanism, with lateral SMA wire fixated with a vertical retention focus area to slider plate, front view inactivated.
10.1DC- Break away one time use mechanism slider plate, inactivated, top view.
10.1DD- Break away one time use mechanism slider plate, activated, top view.
10.1DE- Retention focus joint.
10.1DF- Retention focus joint, fixation depression.
10.1DG- Guide channel.
10.1DH- Slider plate with guide channel.
10.1DI- Extension spring.
10.1E- One time use break away mechanism, with preformed SMA bend for retention.
10.1EA- One time use break away mechanism, with preformed SMA bend for retention, side view, activated.
10.1EB- One time use break away mechanism, with preformed SMA bend for retention, side view, activated (spring shown exploded, for clarity).
10.1EC- Retention bend in SMA wire.
10.1F- One time use break away mechanism with SMA plate.
10.1FA- Side view of inactivated one time use break away mechanism with an SMA plate.
10.1FB- top view of inactivated plate showing the reataining body, stopped.
10.1FC- Side view of actiavted one time use break away meachnsim with an SMA plate.
10.1FD- top view of actiavted plate showing the opening of the plate upon activation.
10.1FE- SMA plate.
10.1FG- Retention body.
10.1FH- Slider plate.

10.1FI- Extenision spring applicable to this mechanism.

Figure

11- Side view of top and bottom connection point options.
11A- Top view of top bottom connection point option.
11AA- Cross sectional view of separated top bottom conduction point options.
11B- Side view of top and full needle body conduction point options.
11C- Top view of separated top bottom conduction point options.
11CA- Cross sectional view of separated top and full needle body conduction point options.
11D- Side view of 3 piece conduction point options.
11E- Top view of separated 3 piece conduction point option.
11EA- Cross sectional view of separated 3 piece conduction point option.
11F- Transverse cannula.
11G- Entire length top bottom
11H- Ring fixation with adhesive.
11I- Glue and teeth fixation.
11J- Glue only fixation.
11K- Other standard crimping fixation.
11L- Grasping teeth close-up cross-sectional view.
11M- Midline ring.
11N- Top plate.
11O- bottom plate.
11P- Left side panel.
11Q- Right side panel.
11R- Contact, joining point, (not shown in all figures)
11S- Ring.
11T- Ring side view.
11U- Joining space.
11V- Joining teeth

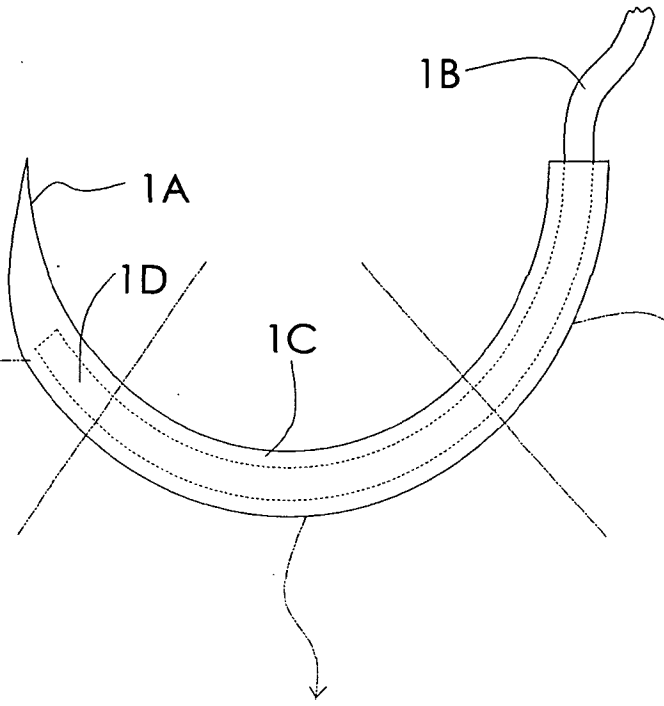


FIG. 3-8

FIG. 11

FIG. 9 & 10

FIG.1I

FIG. 1J

FIG.1K

FIG. 1L

FIG. 1

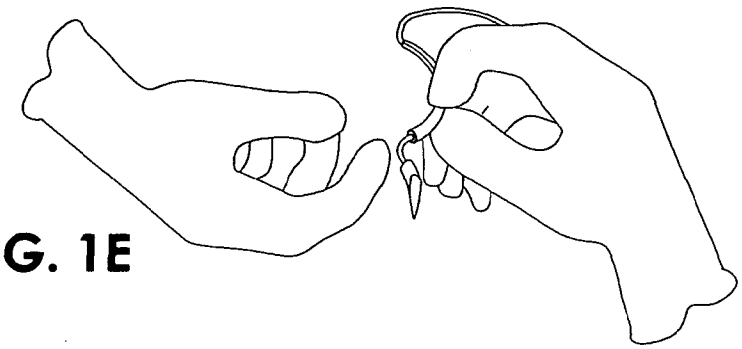


FIG. 1E

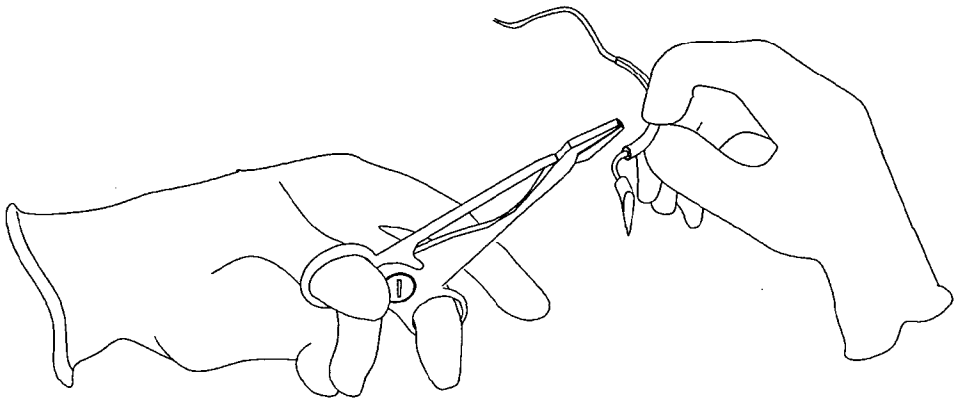


FIG. 1F

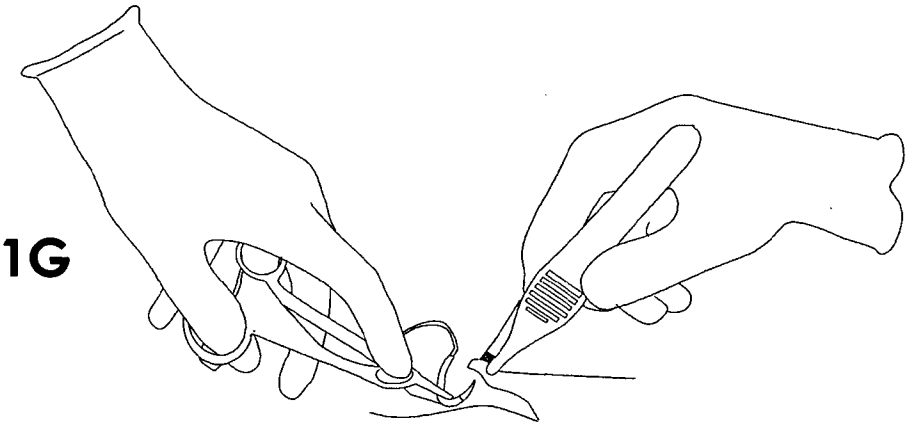


FIG. 1G

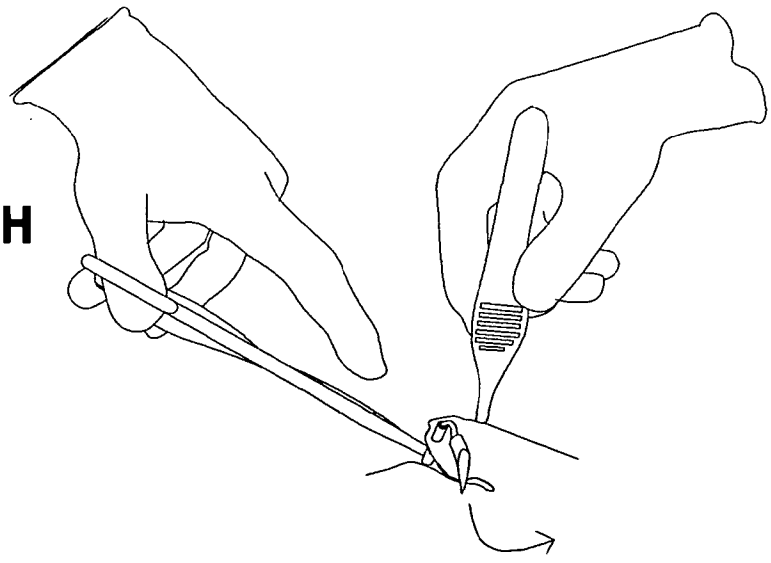


FIG. 1H

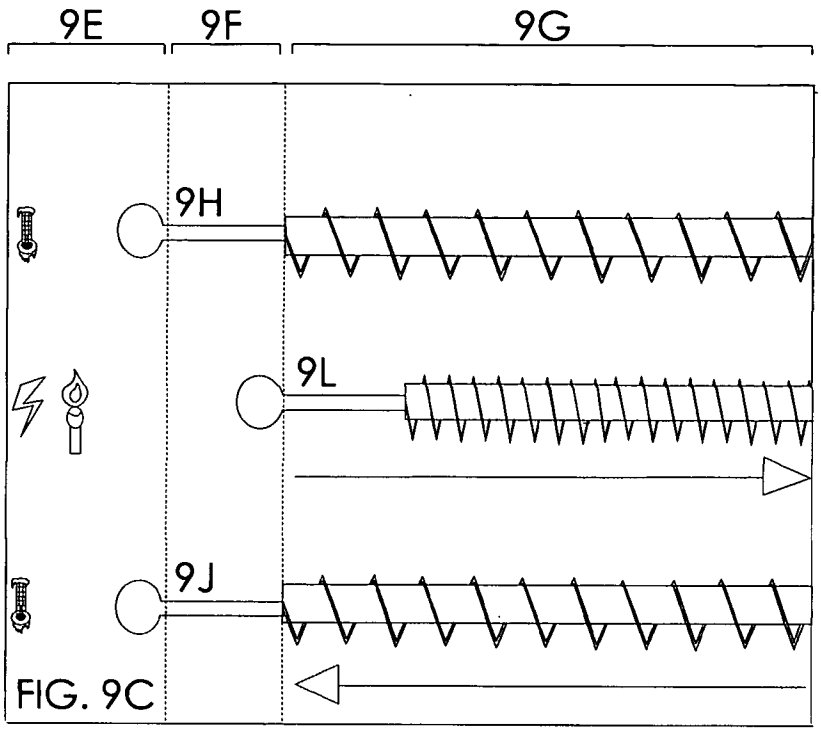


FIG. 9C

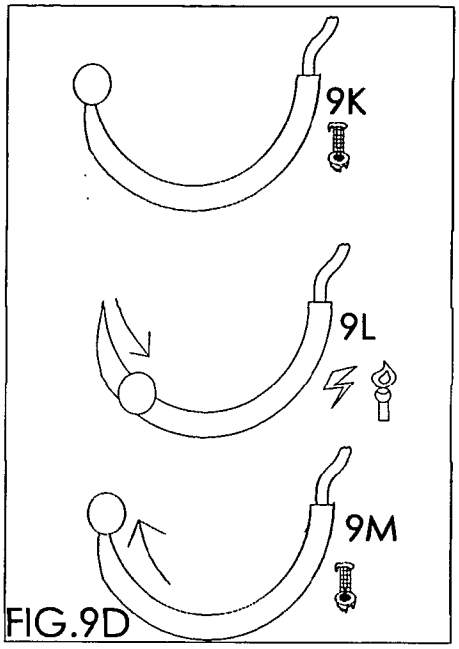


FIG.9D

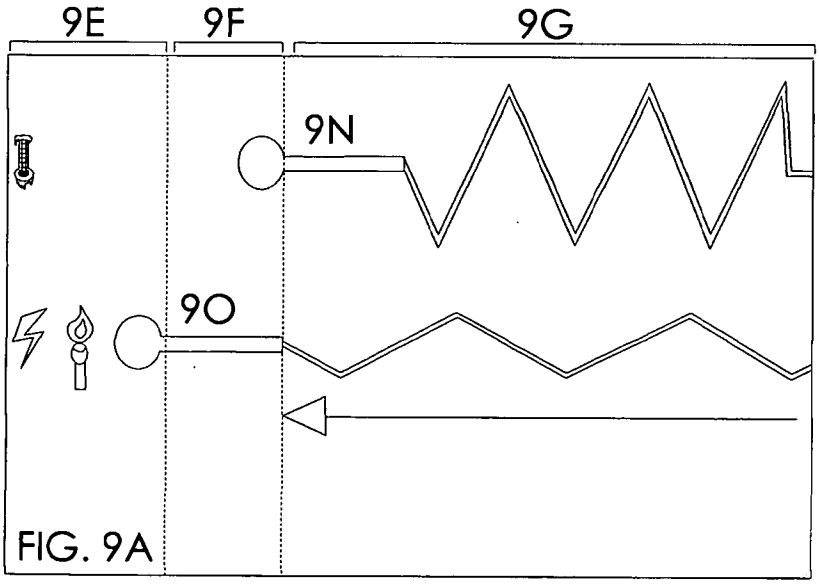


FIG. 9A

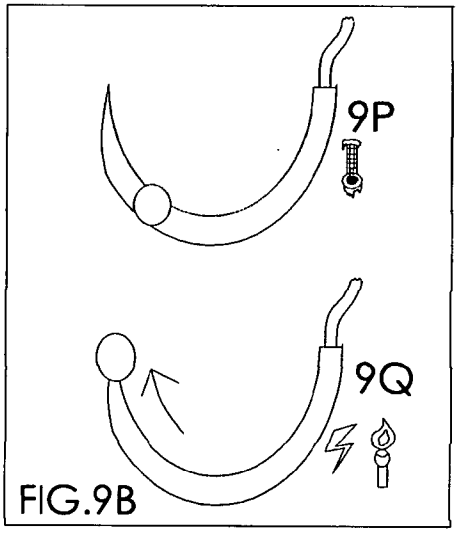


FIG.9B

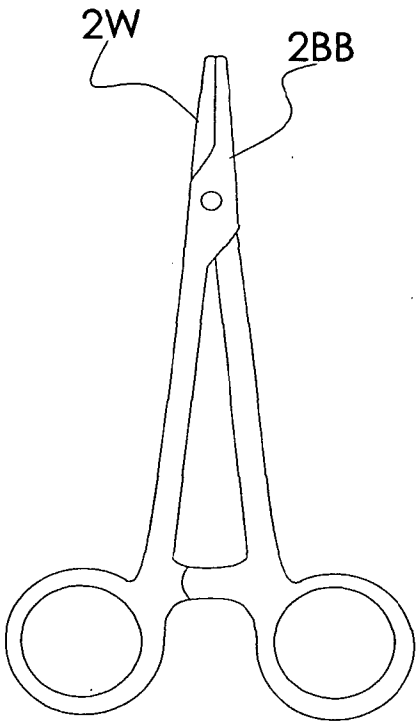


FIG 2

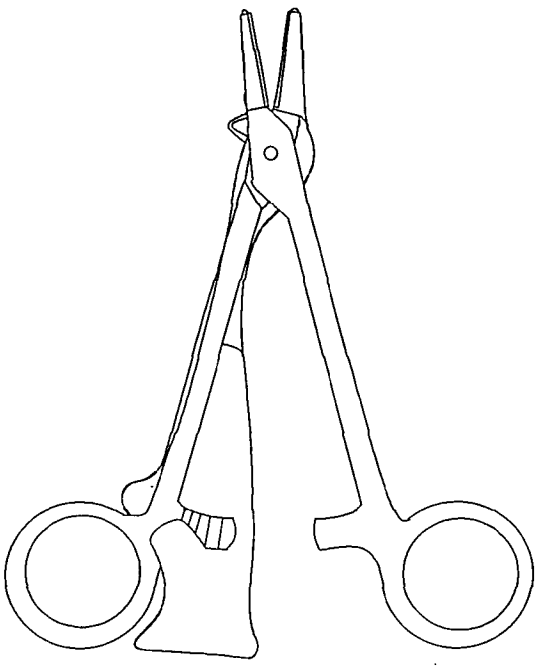


FIG 2A

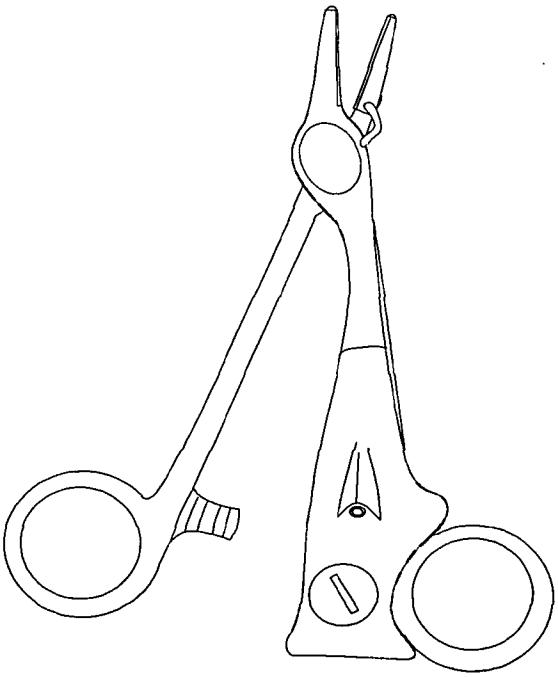


FIG 2B

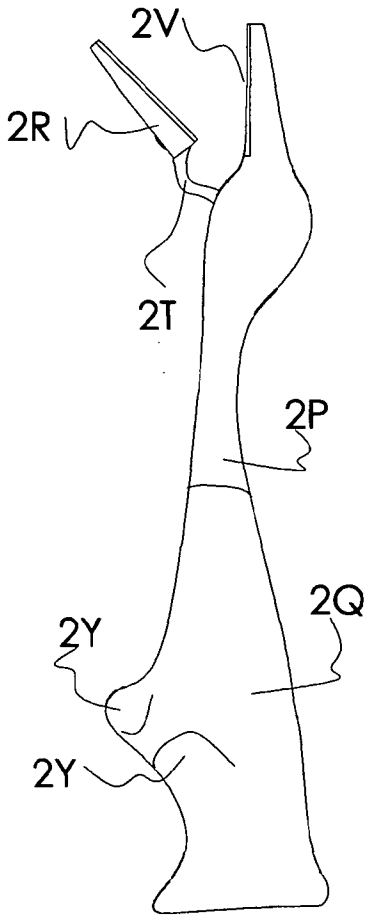


FIG. 2C

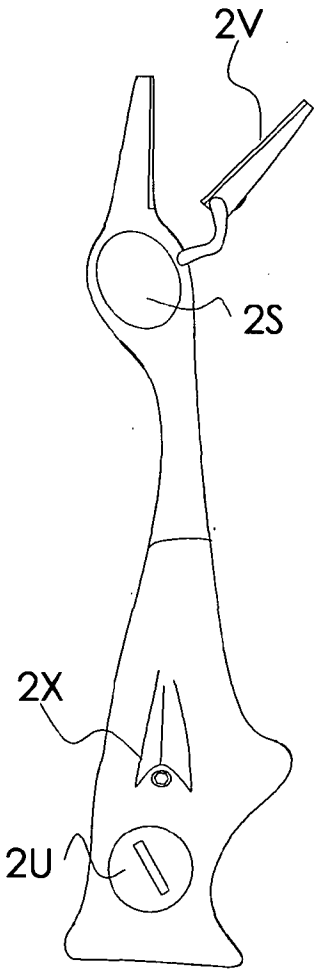


FIG. 2D

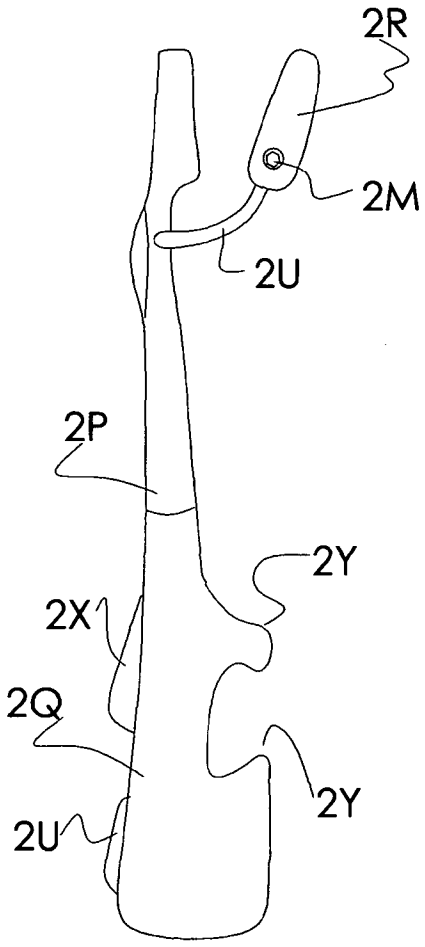


FIG. 2E

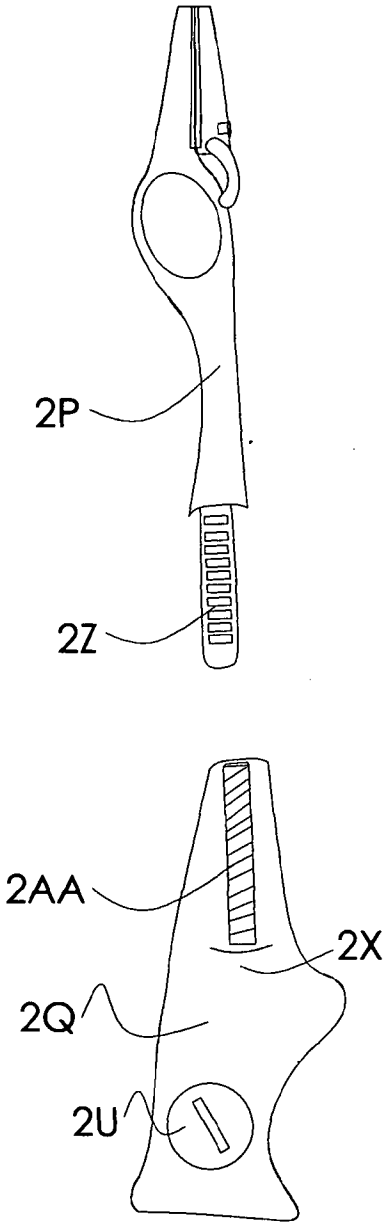


FIG. 2F

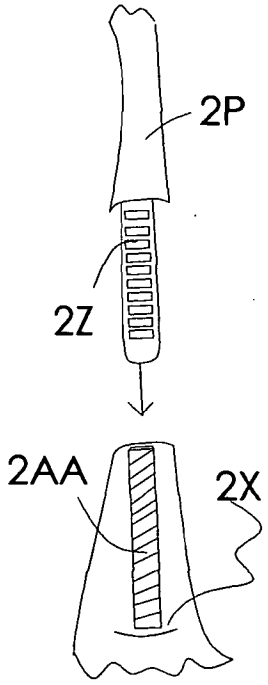


FIG. 2G

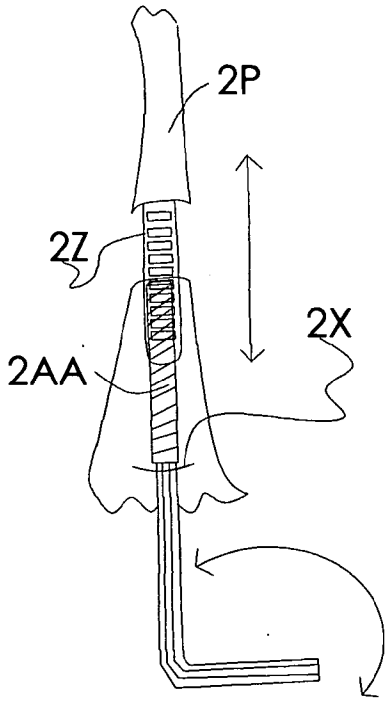


FIG. 2H

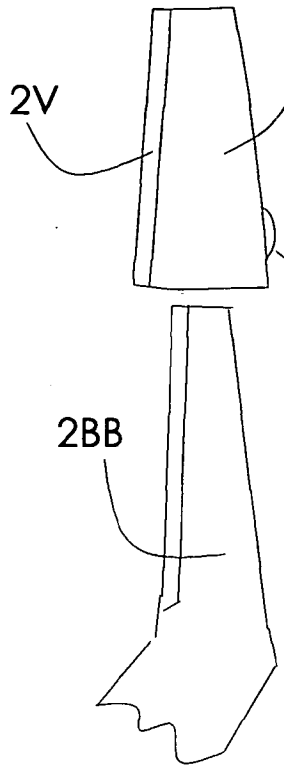


FIG. 2J

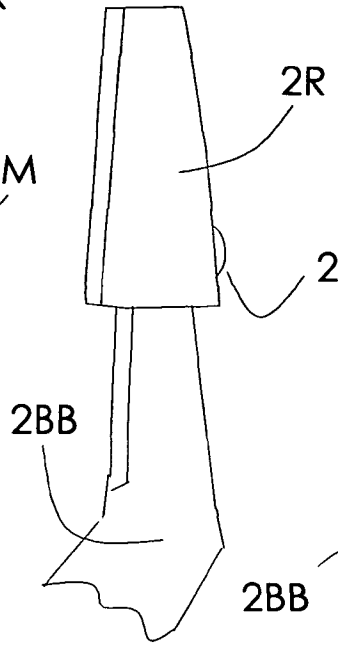


FIG. 2K

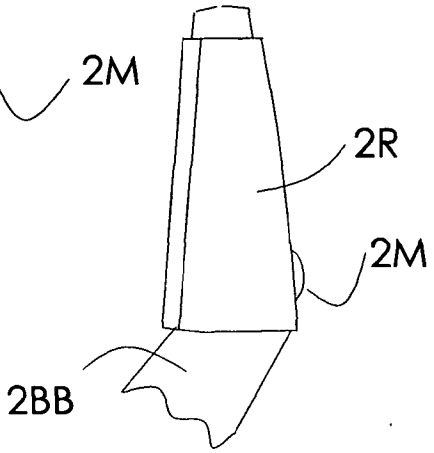


FIG. 2L

FIG. 2I

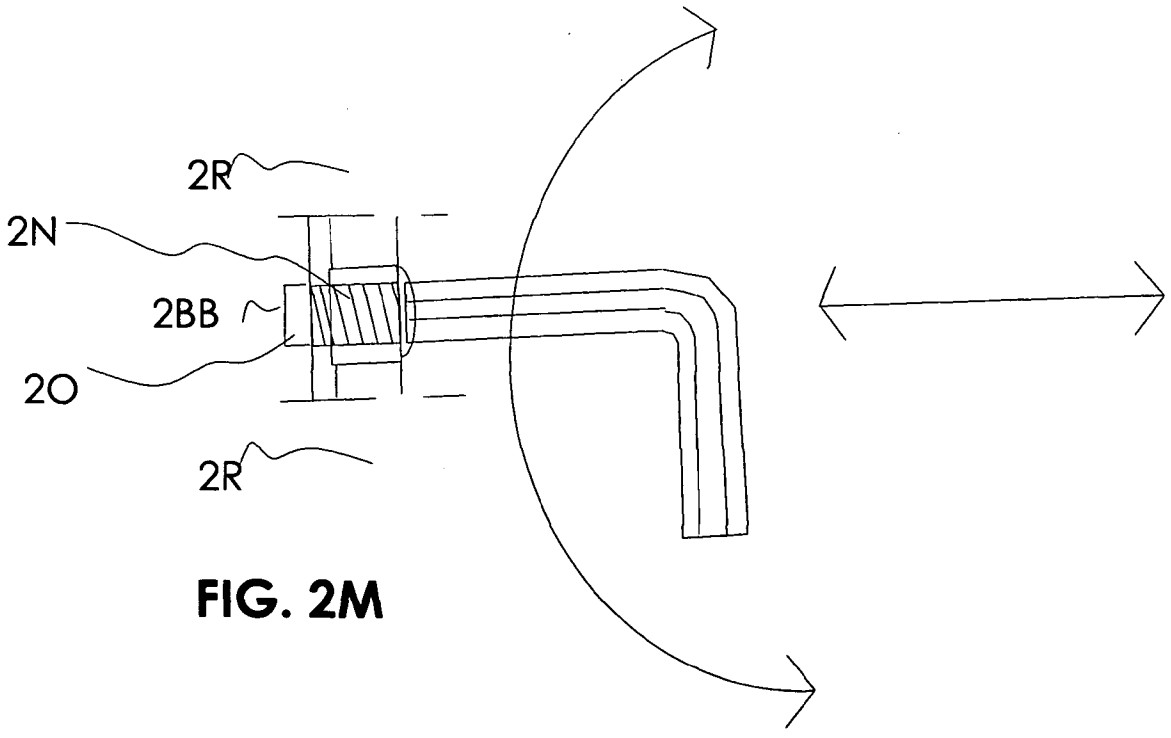


FIG. 2M

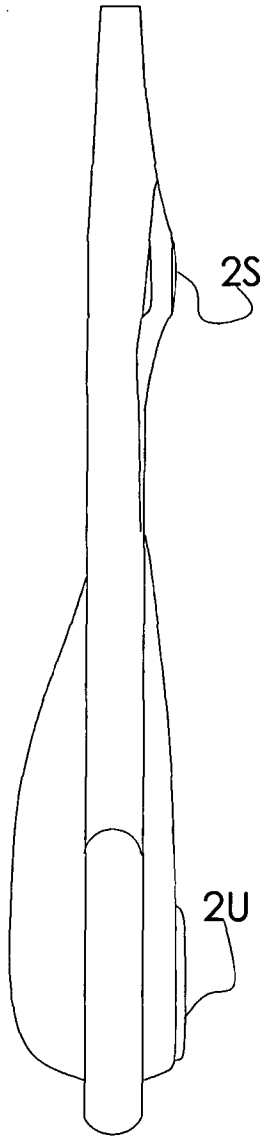


FIG. 2.1

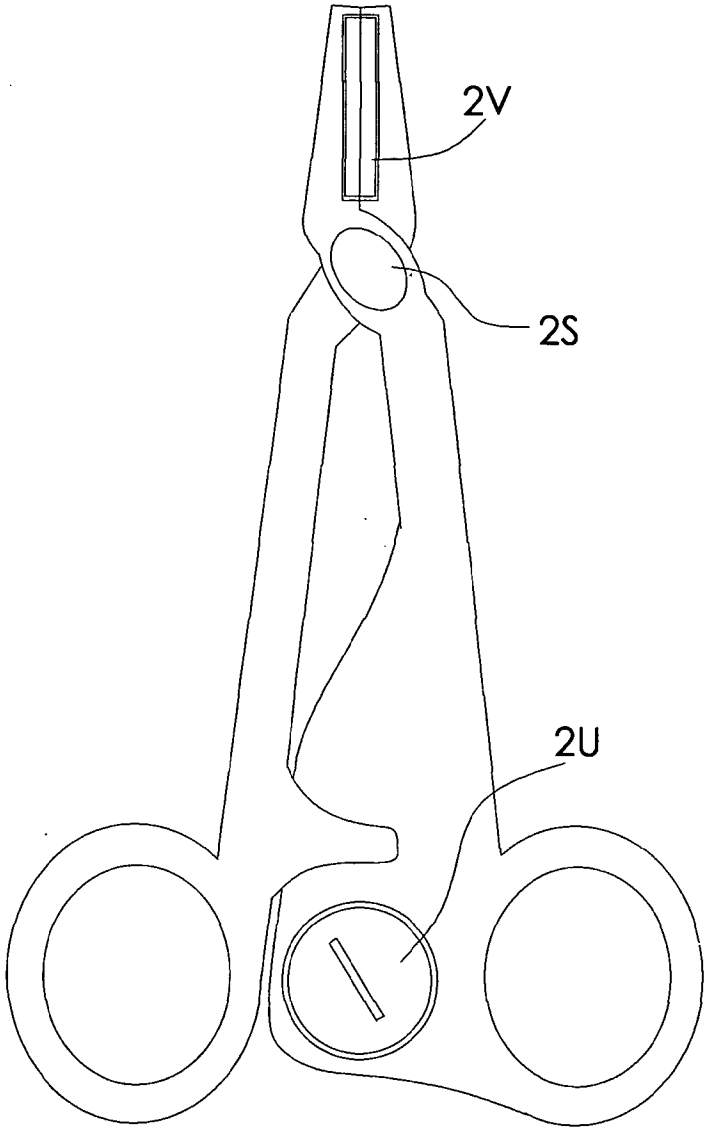


FIG. 2.1A

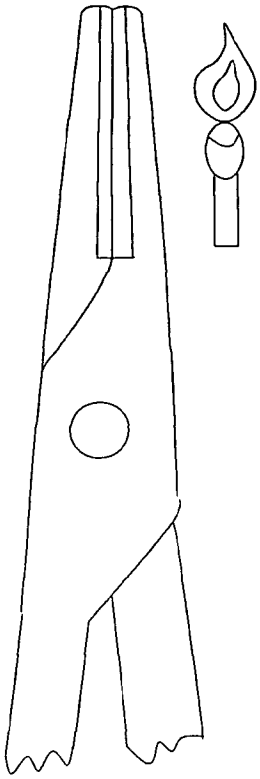


FIG. 2.2

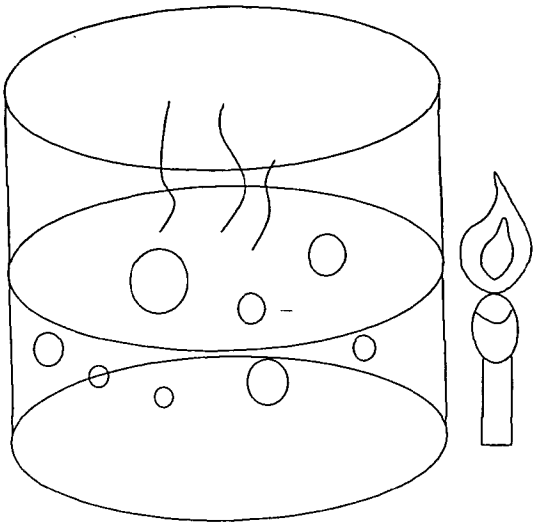


FIG. 2.2B

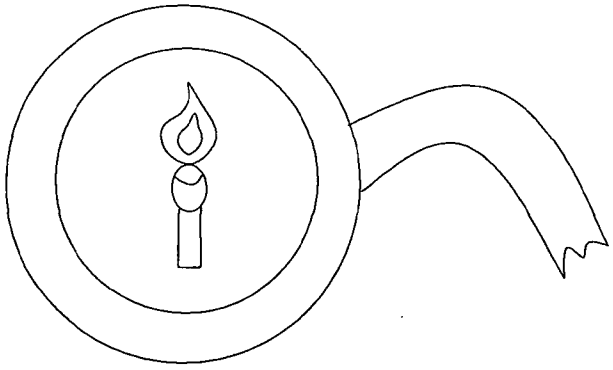


FIG. 2.2A

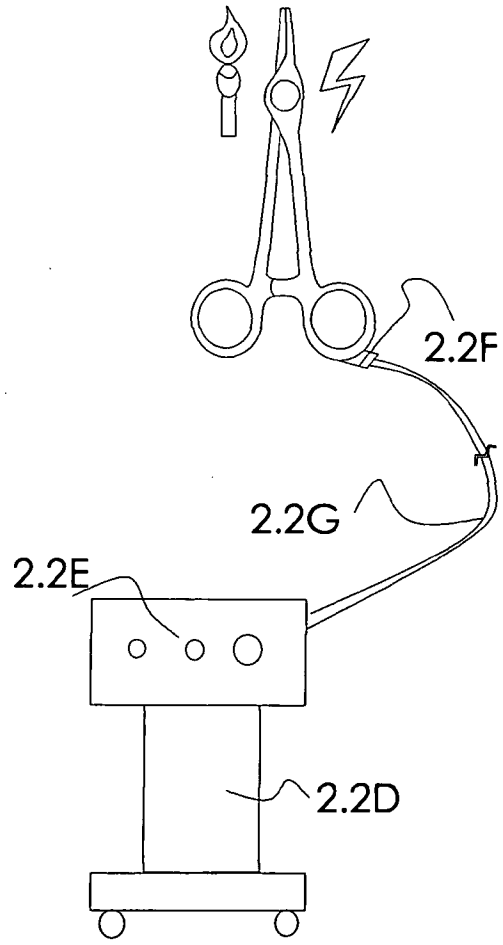


FIG. 2.2C

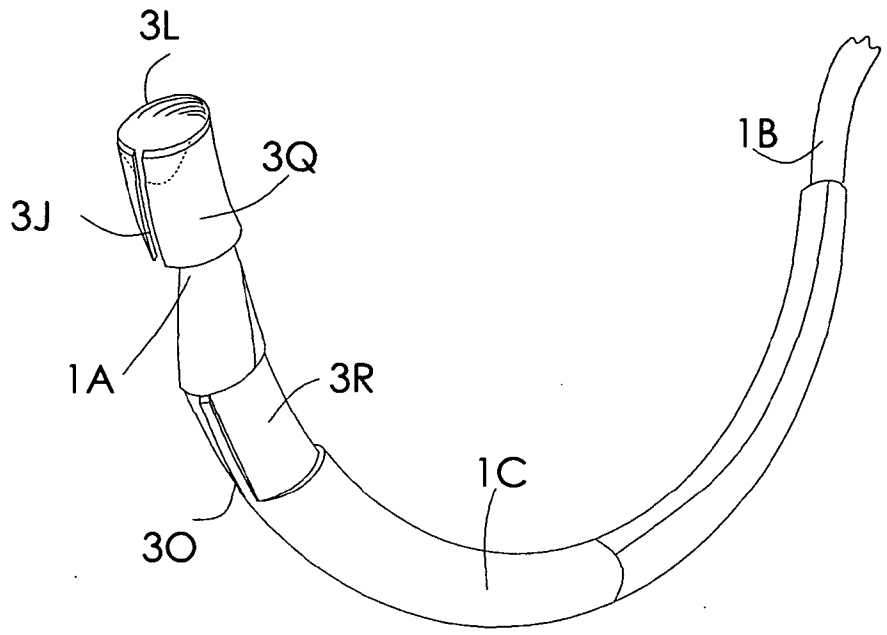


FIG. 3

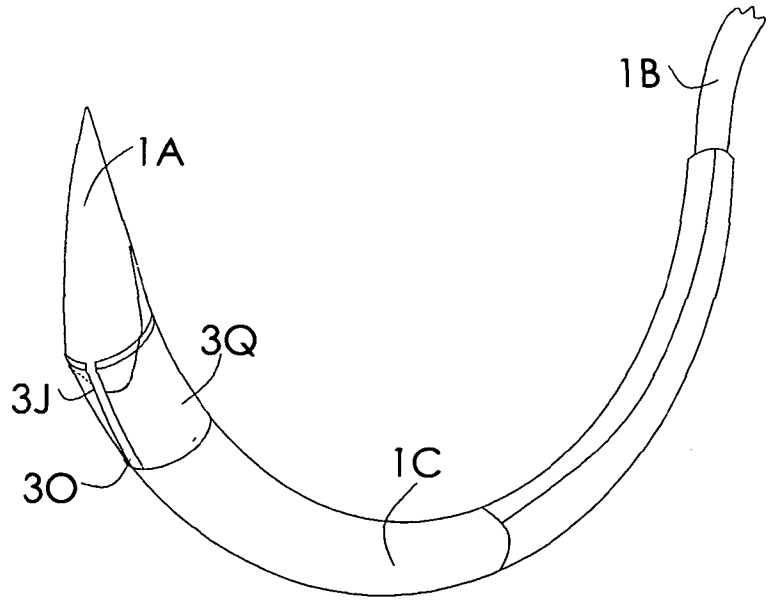


FIG. 3A

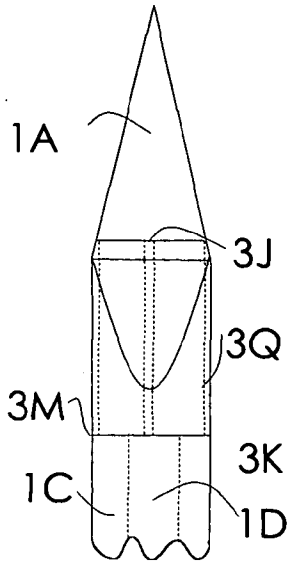


FIG. 3B

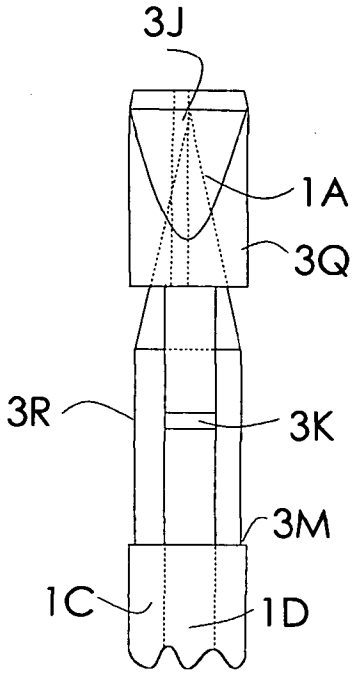


FIG. 3C

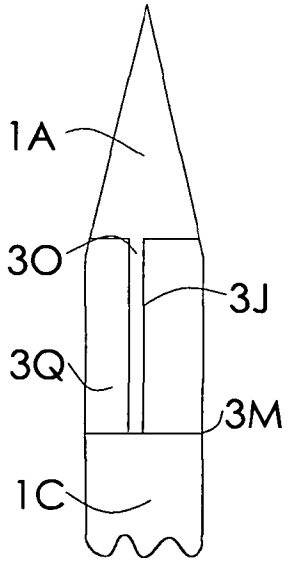


FIG. 3D

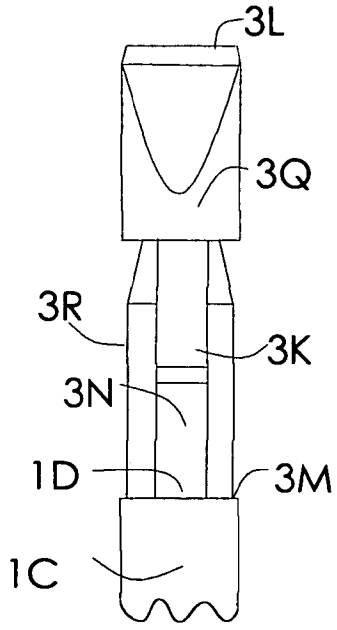


FIG. 3E

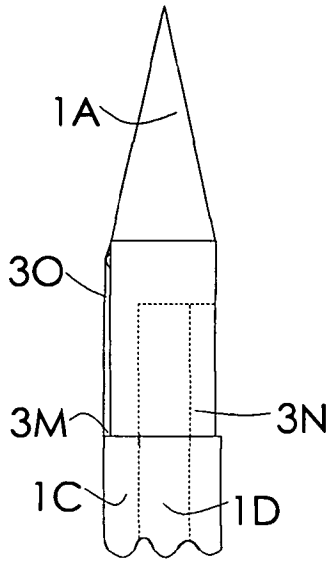


FIG. 3F

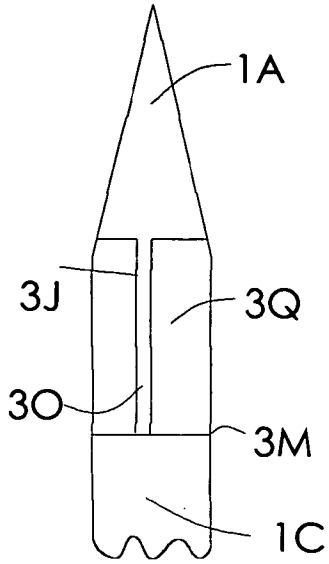


FIG. 3G

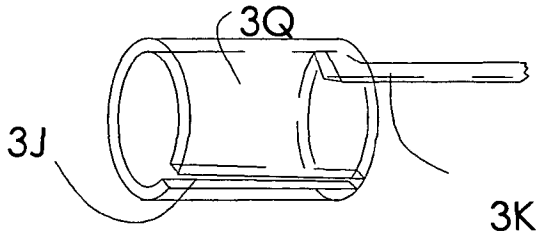


FIG. 3H

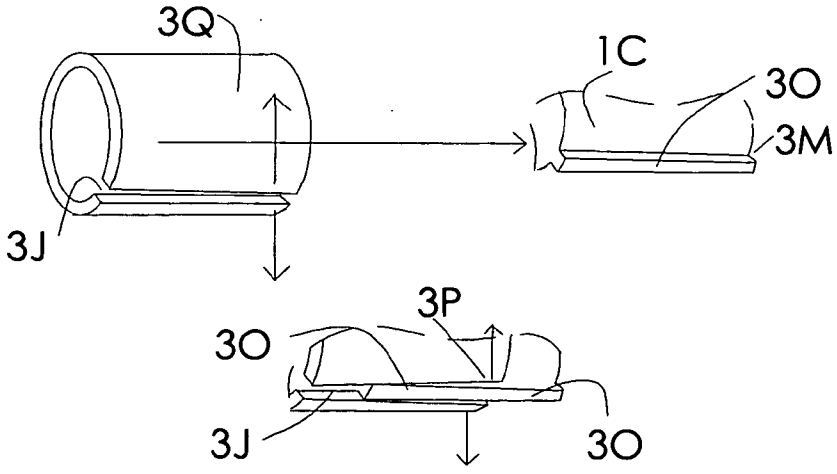


FIG. 3I

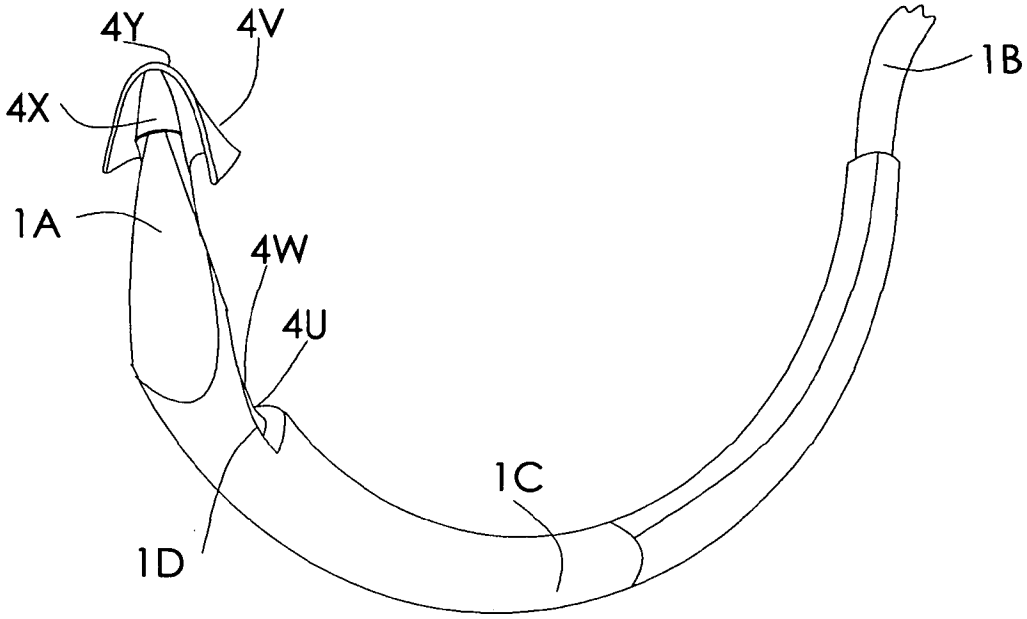


FIG. 4

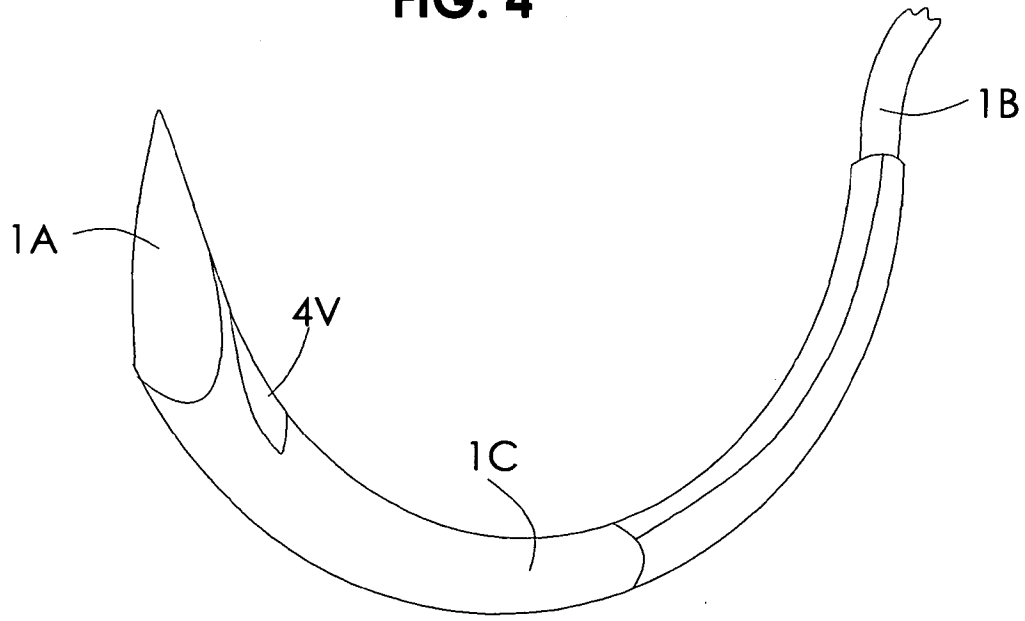


FIG. 4A

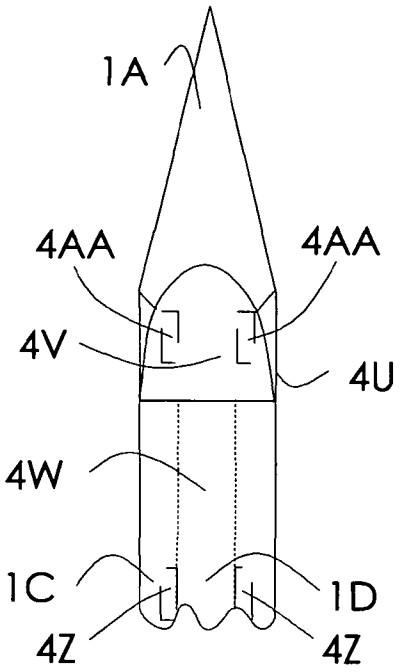


FIG. 4B

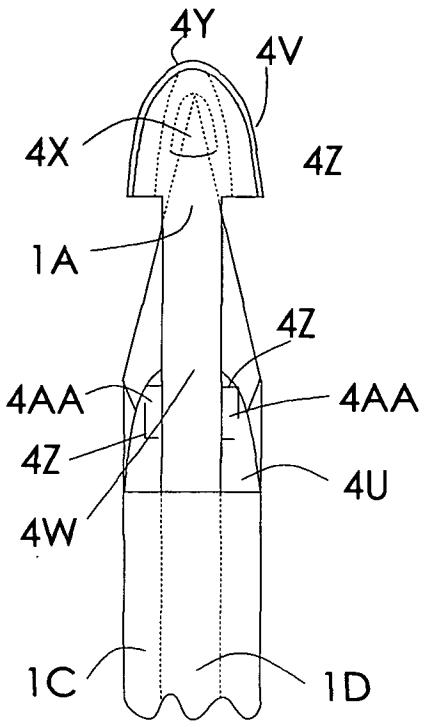


FIG. 4C

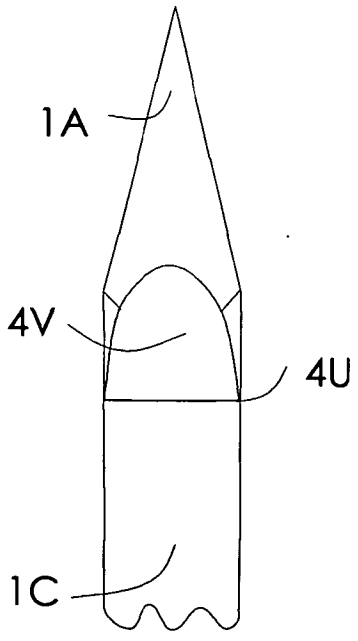


FIG. 4D

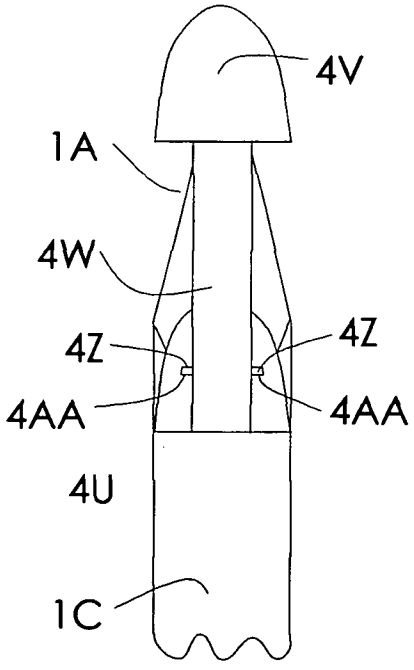


FIG. 4E

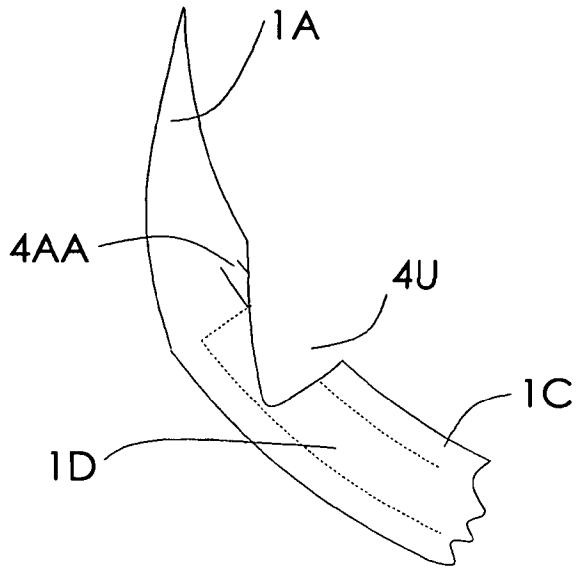


FIG. 4F

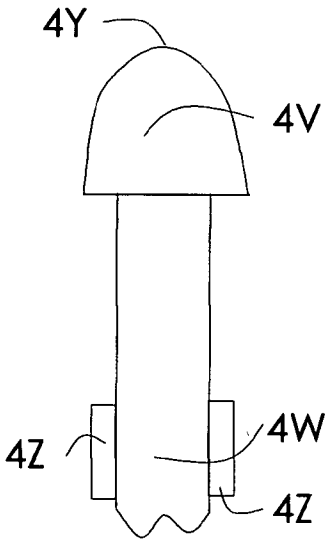


FIG. 4G

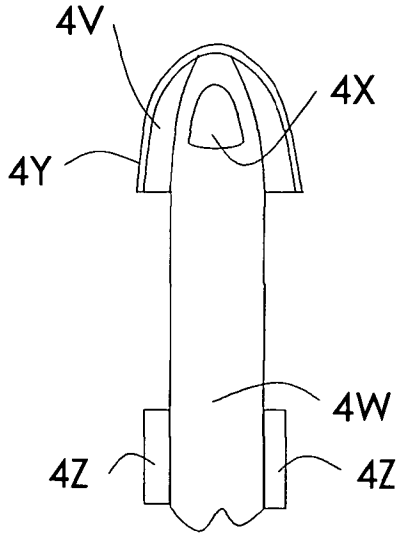


FIG. 4H

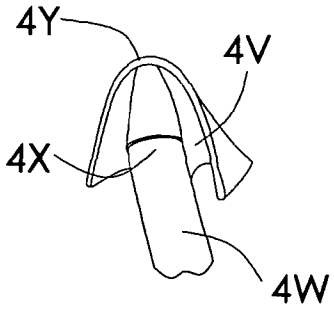


FIG. 4I

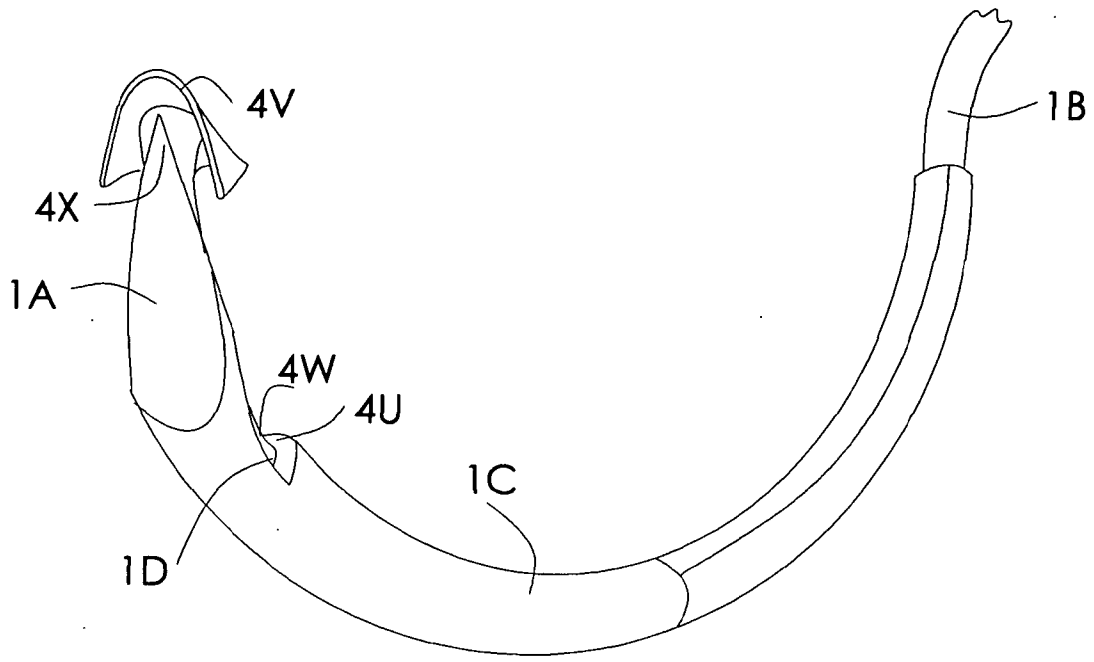


FIG. 4J

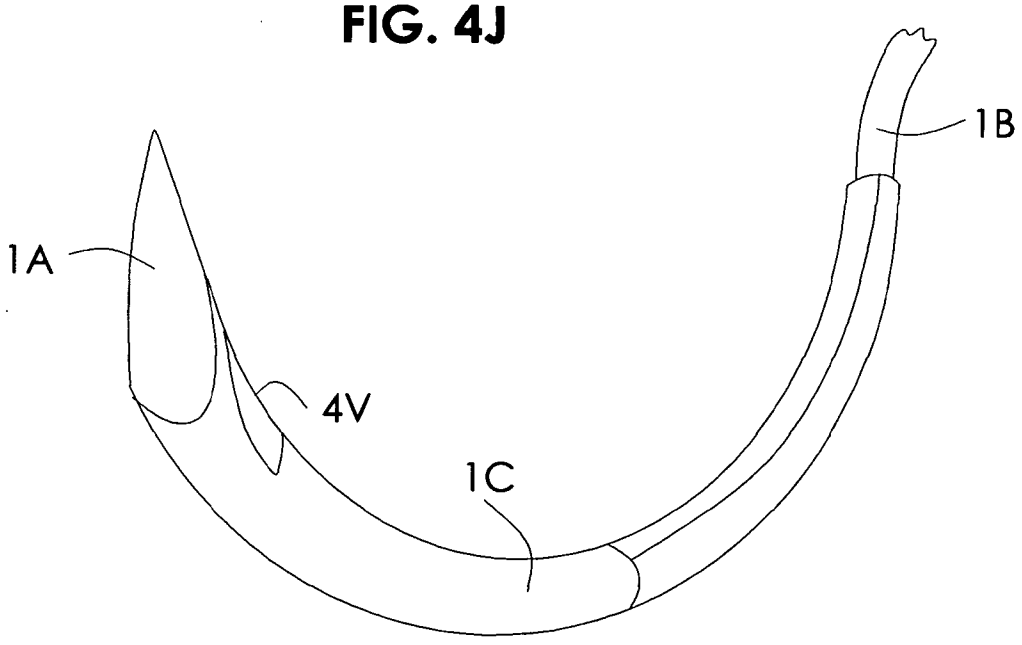


FIG. 4K

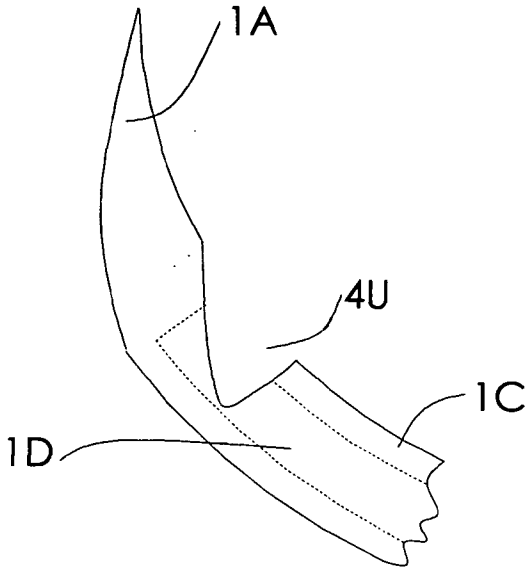


FIG. 4P

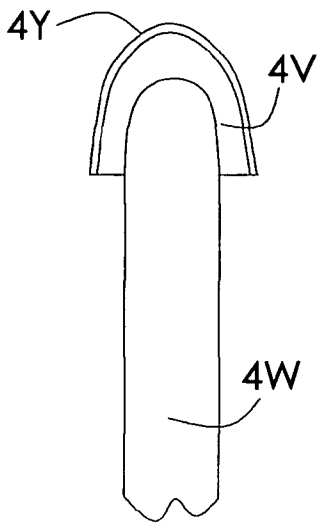


FIG. 4R

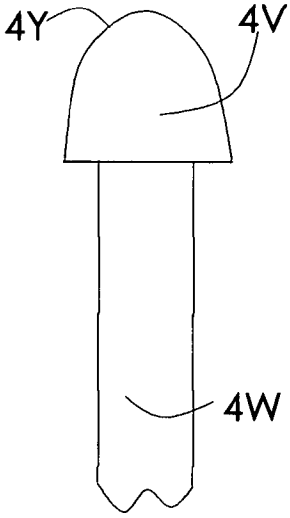


FIG. 4Q

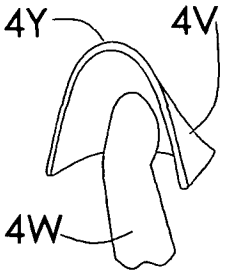


FIG. 4S

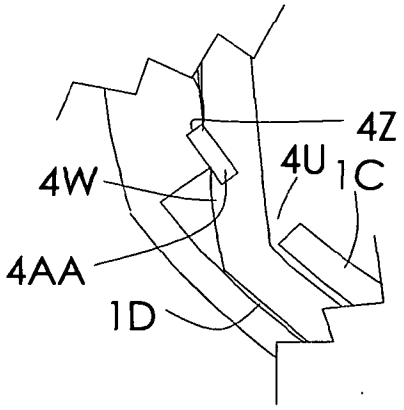


FIG. 4T

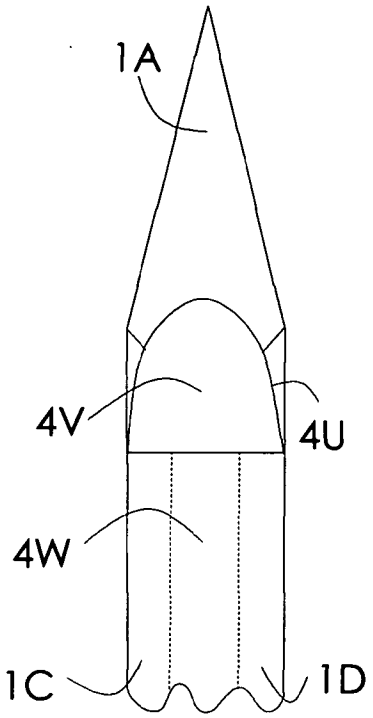


FIG. 4L

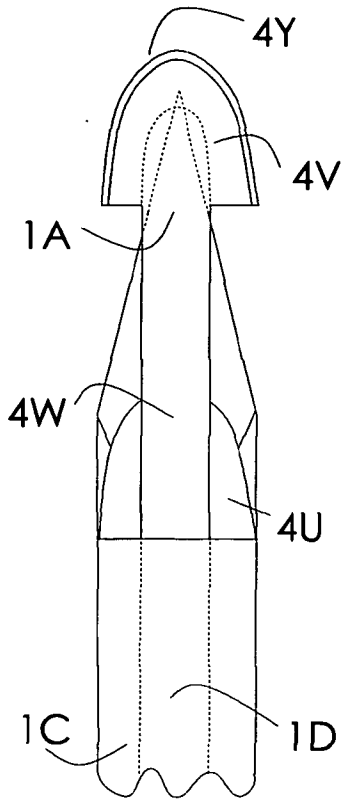


FIG. 4M

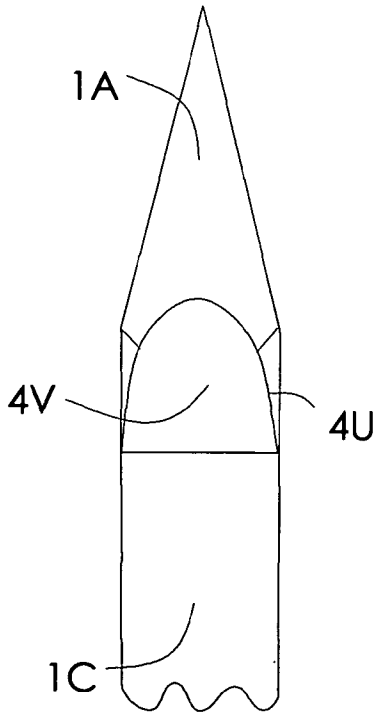


FIG. 4N

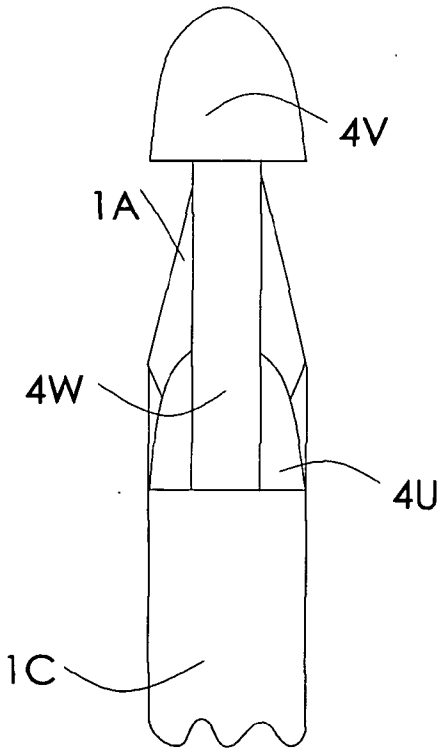


FIG. 4O

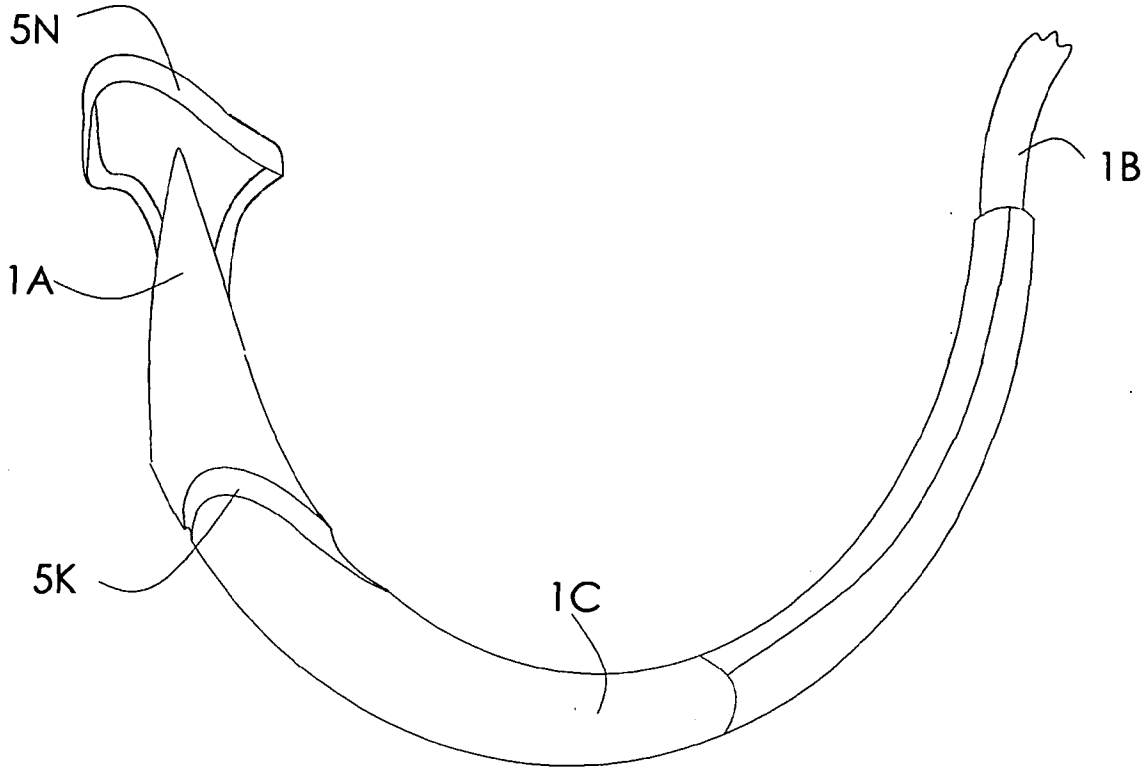


FIG. 5

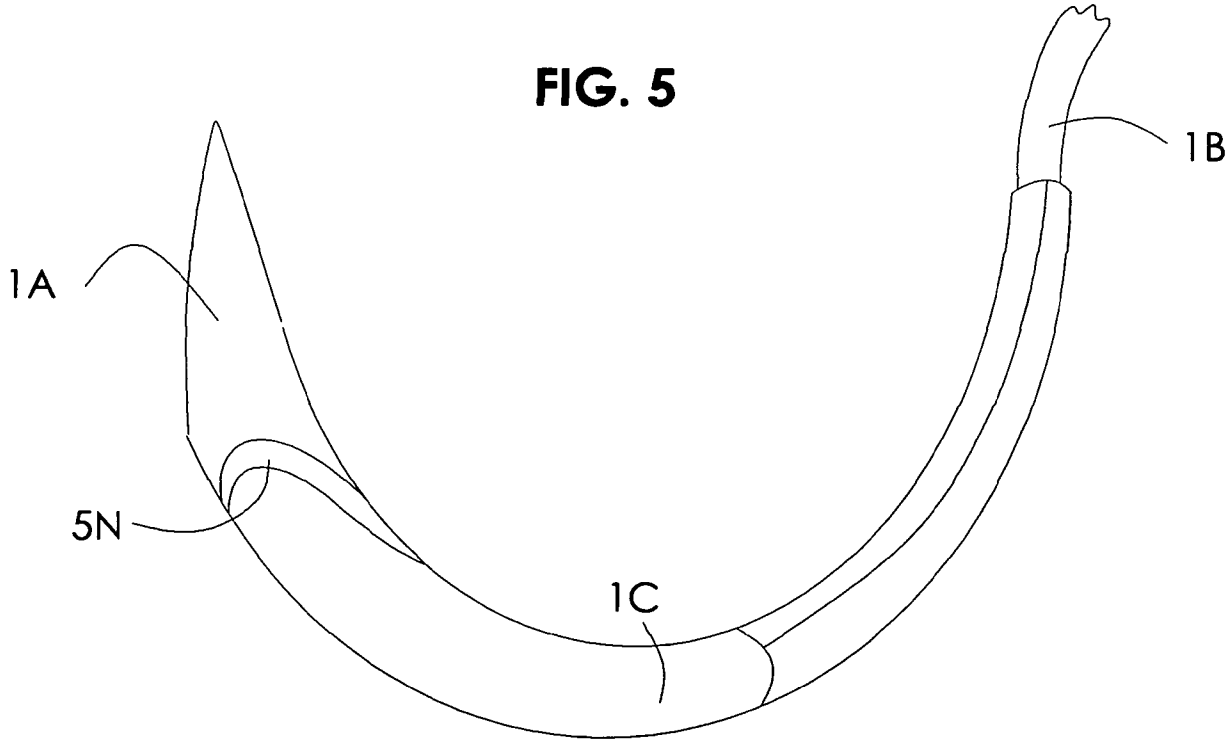


FIG. 5A

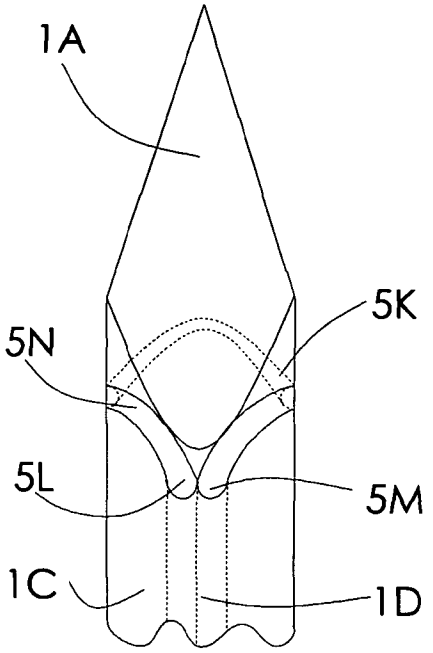


FIG. 5B

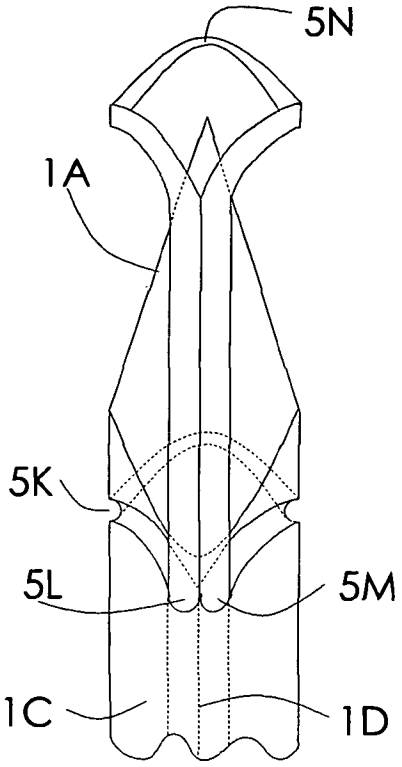


FIG. 5C

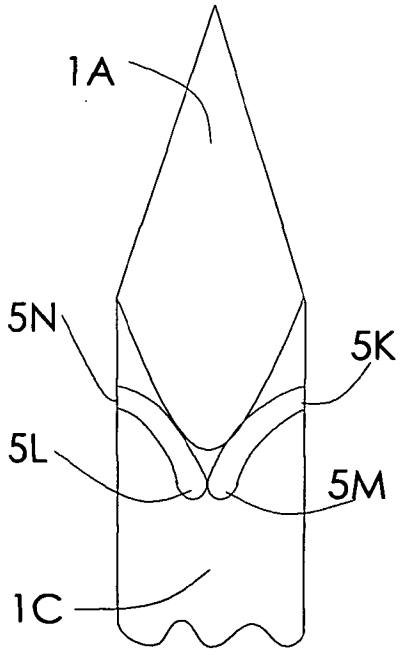


FIG. 5D

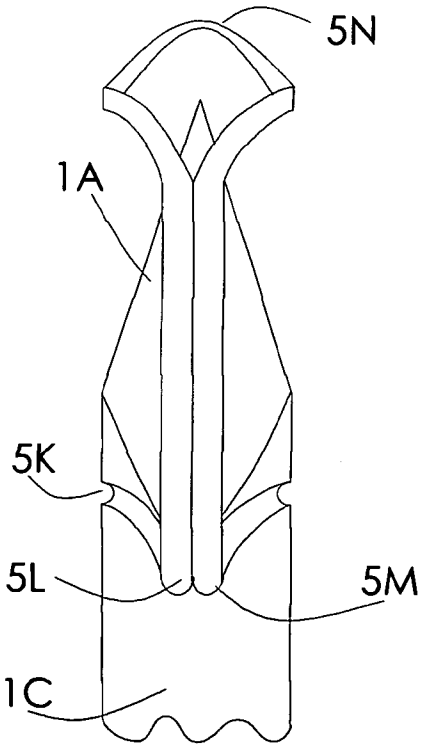


FIG. 5E

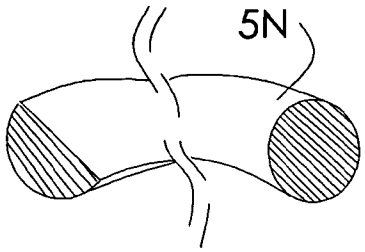


FIG. 5F

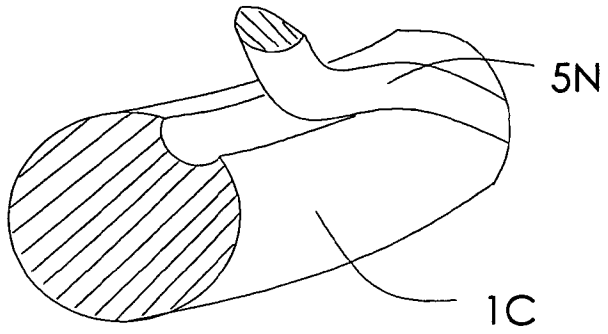


FIG. 5G

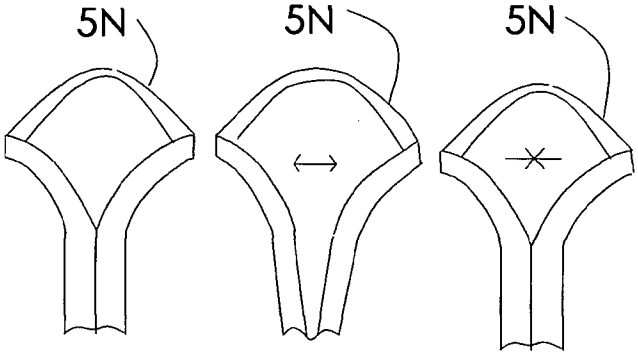


FIG. 5H

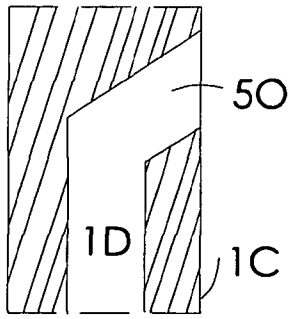


FIG. 5I

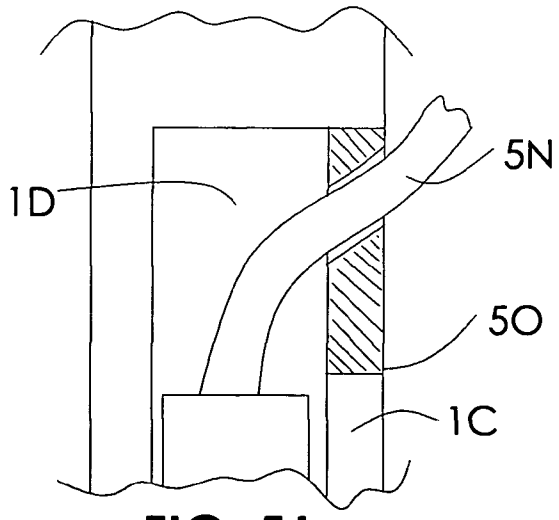


FIG. 5J

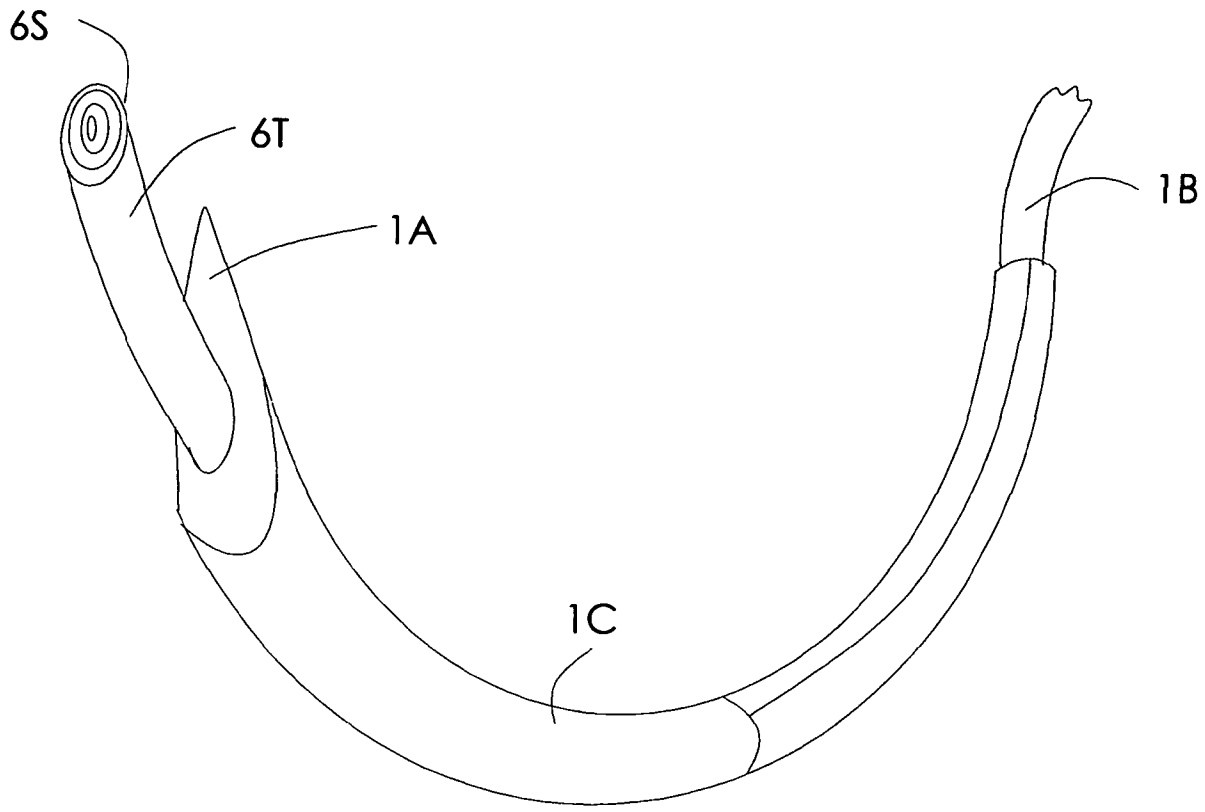


FIG 6

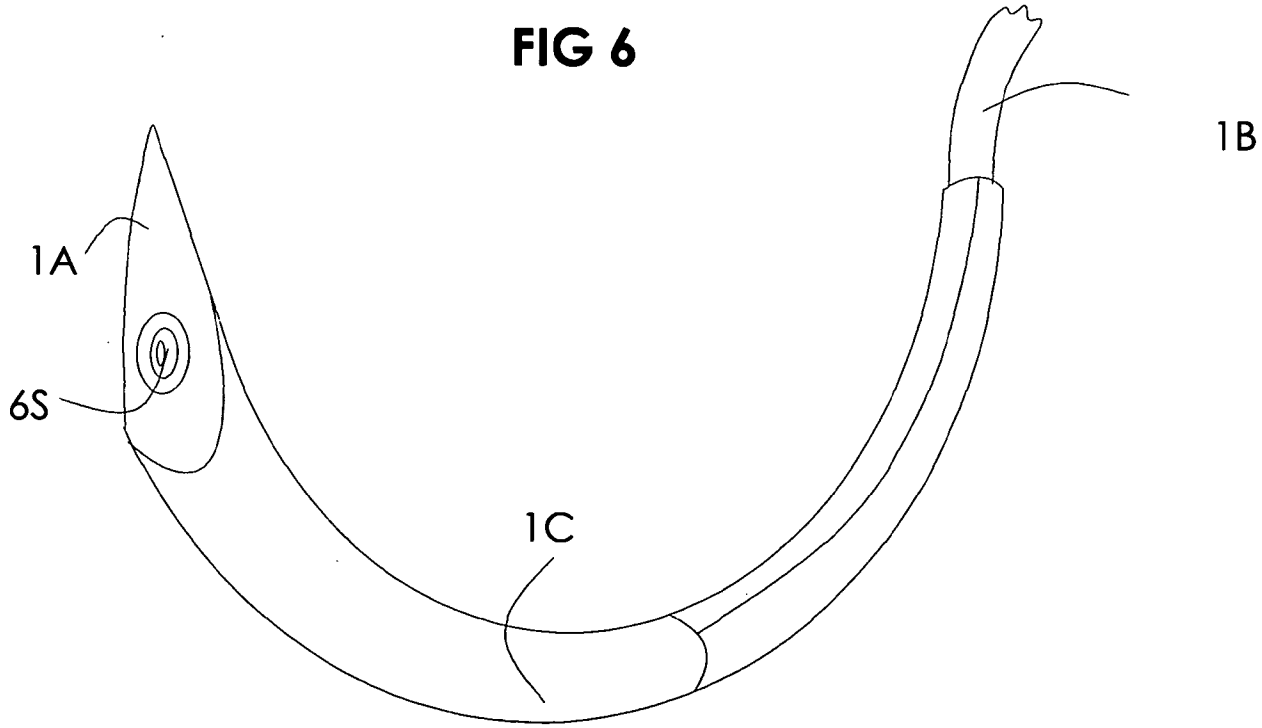


FIG. 6A

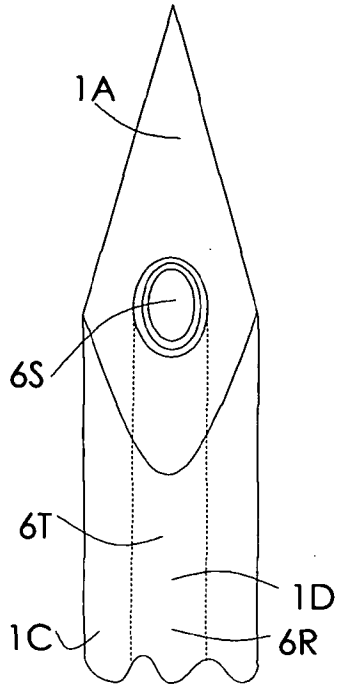


FIG. 6B

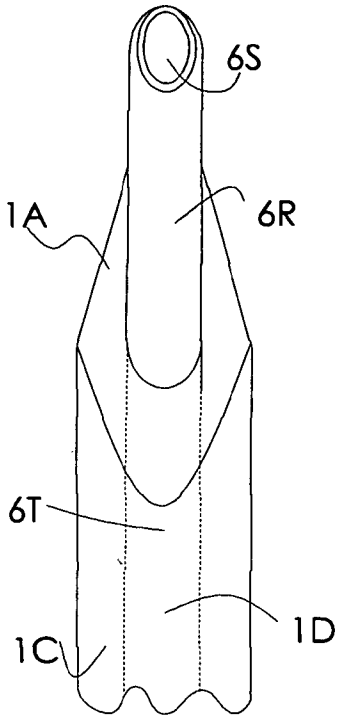


FIG. 6C

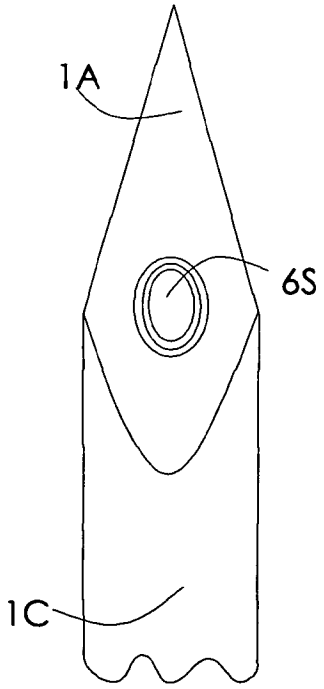


FIG. 6D

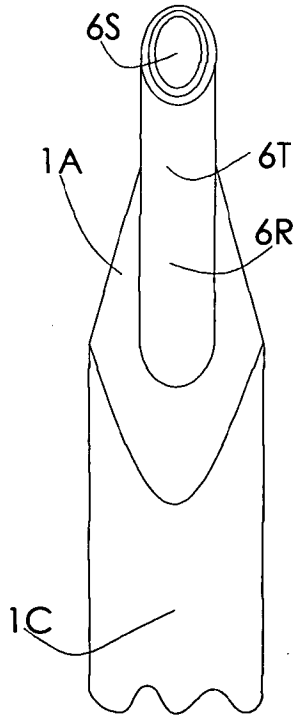


FIG. 6E

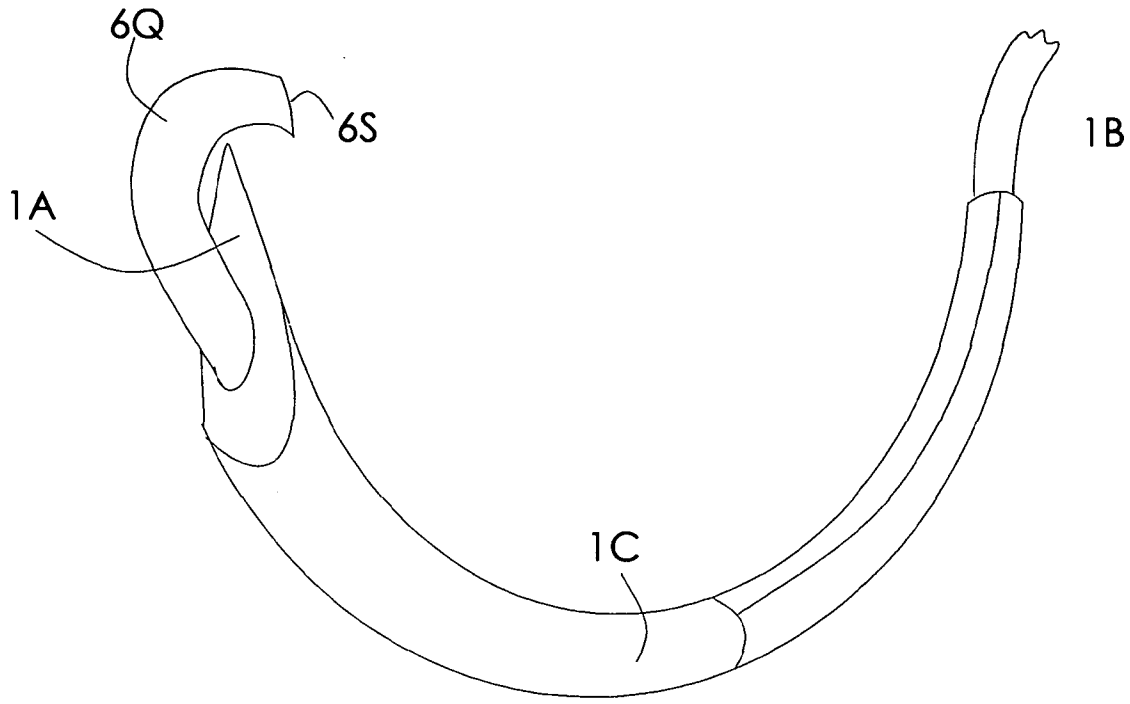


FIG. 6G

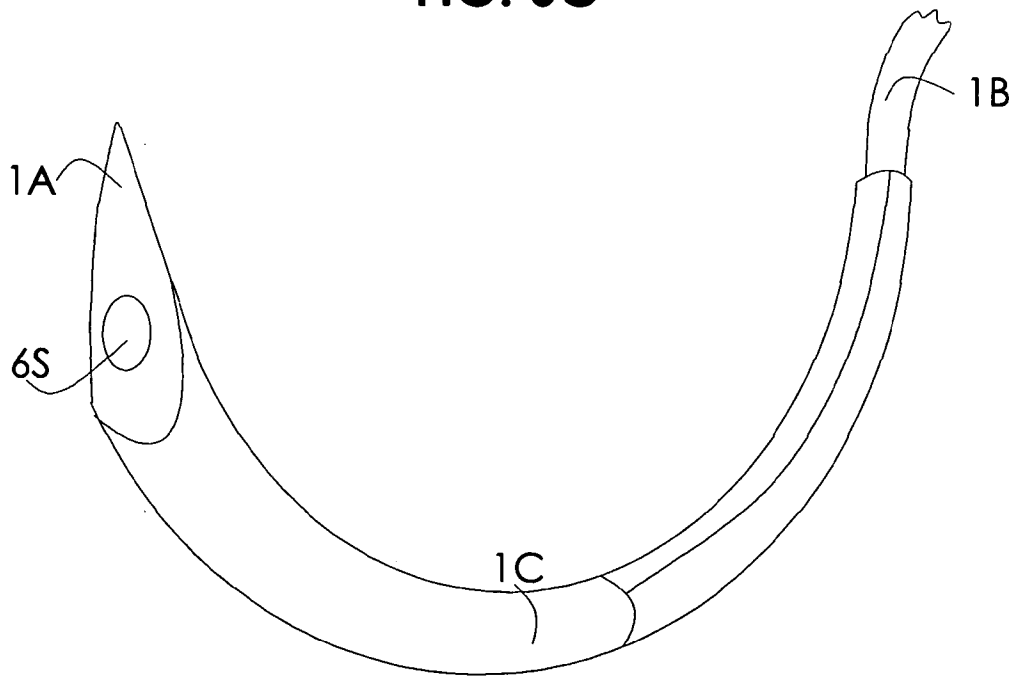


FIG. 6H

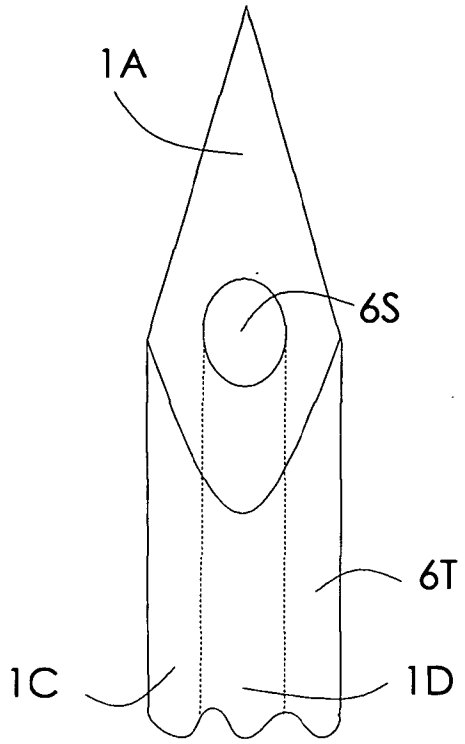


FIG. 6I

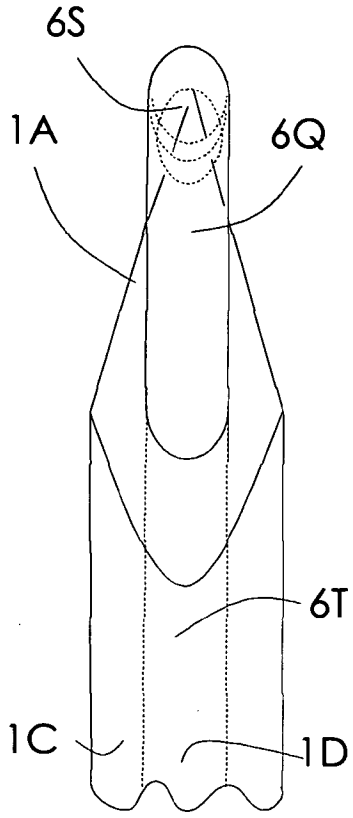


FIG. 6J

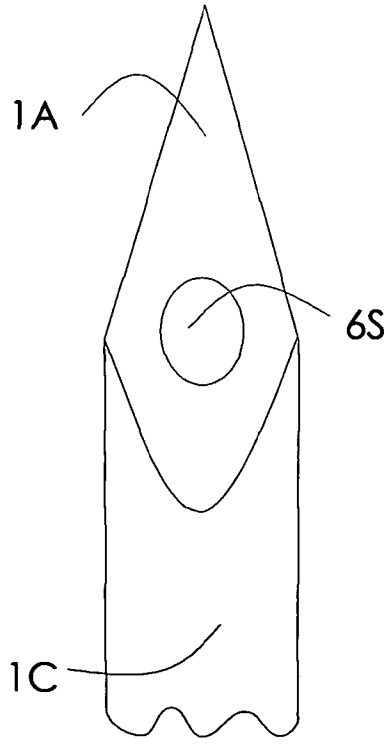


FIG. 6K

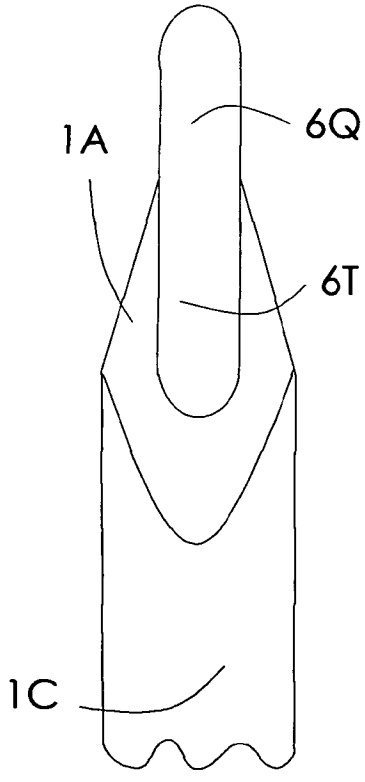


FIG. 6L

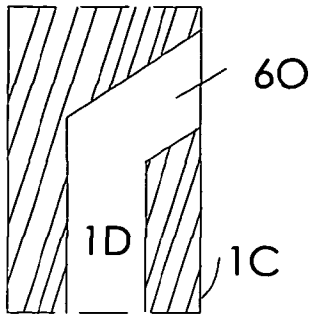


FIG. 6F

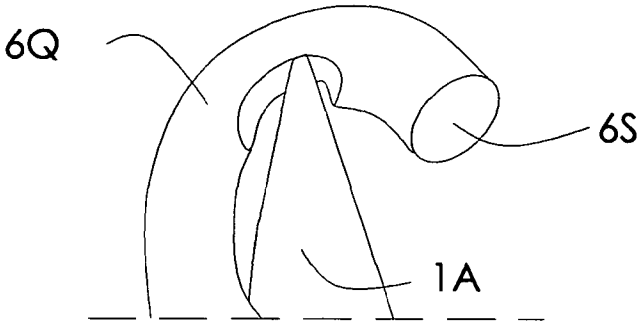


FIG. 6M

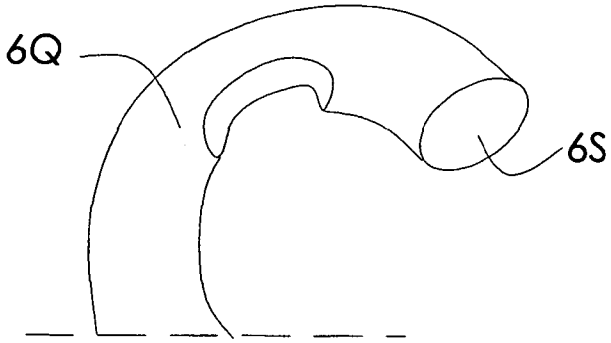


FIG. 6N

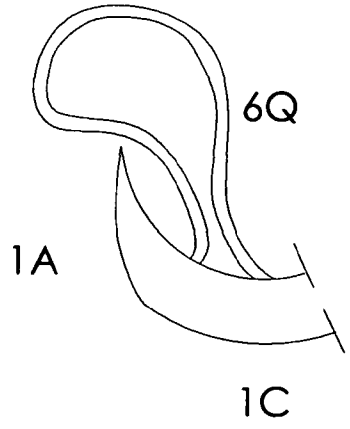


FIG. 6P

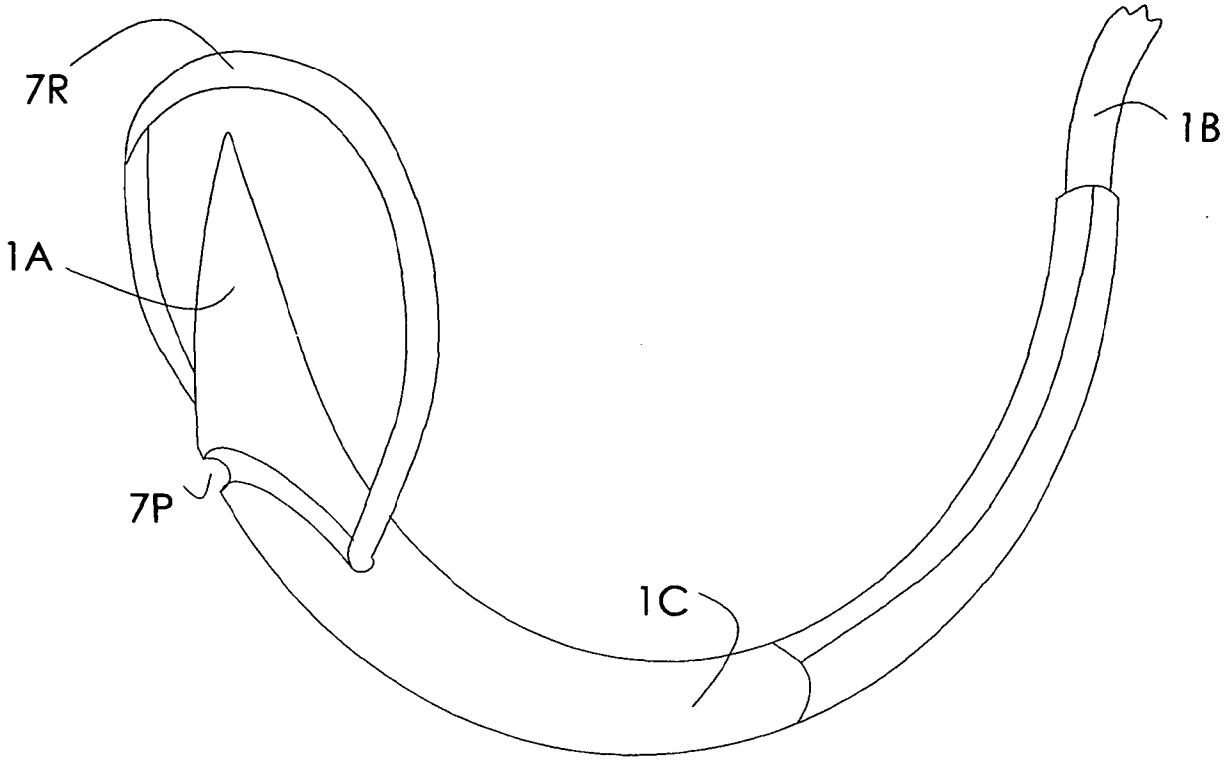


FIG. 7

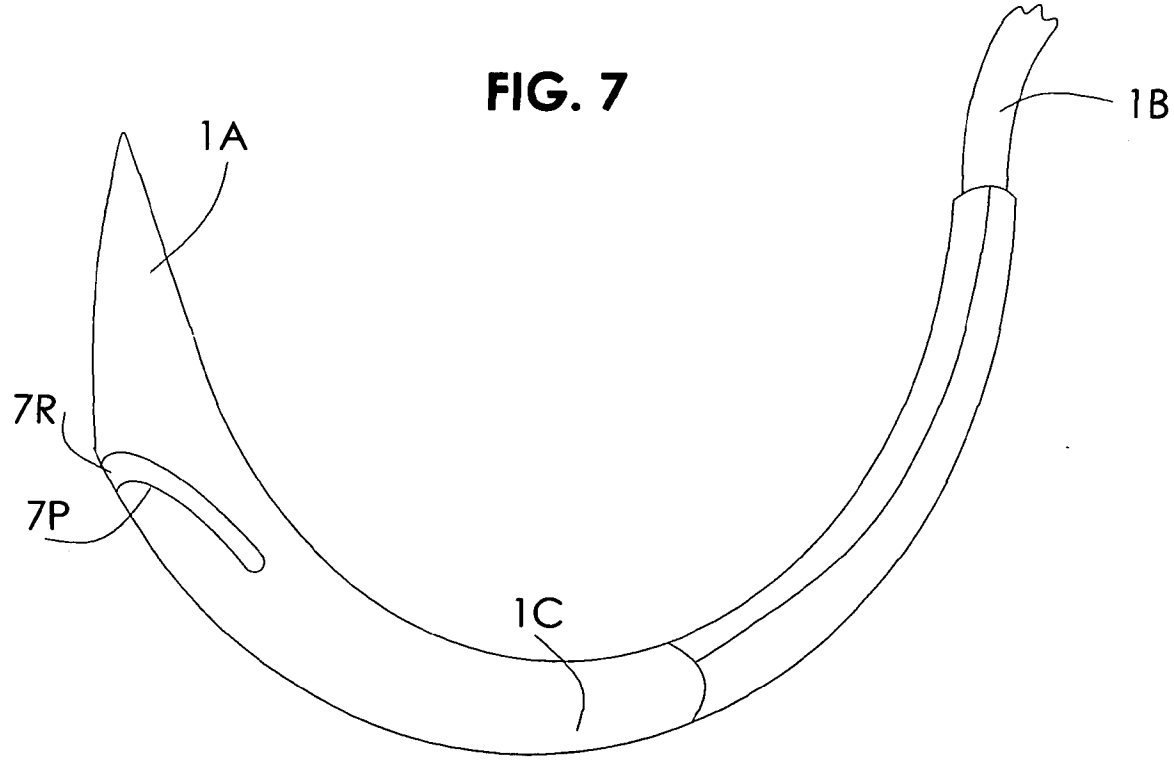


FIG. 7A

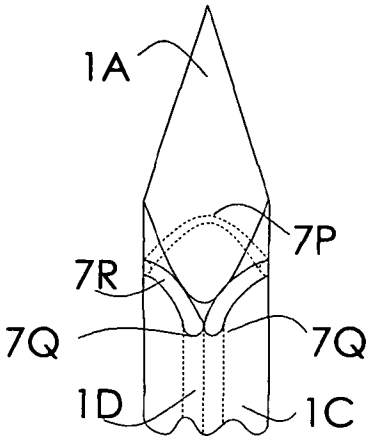


FIG. 7B

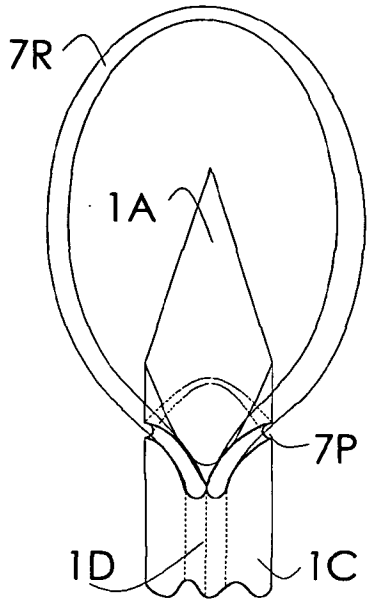


FIG. 7C

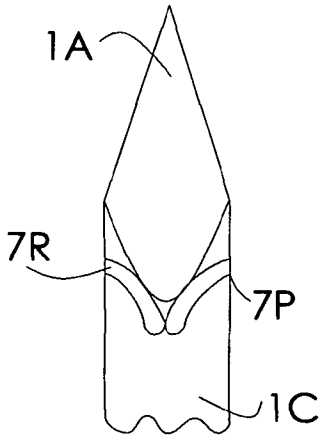


FIG. 7D

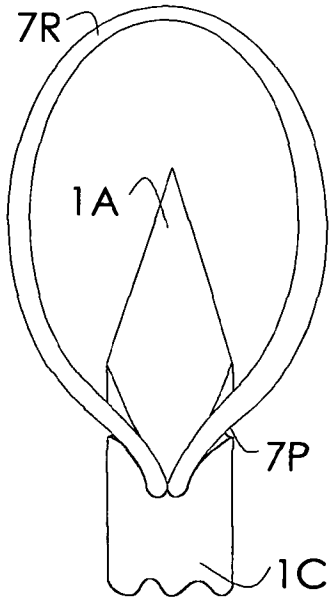


FIG. 7E

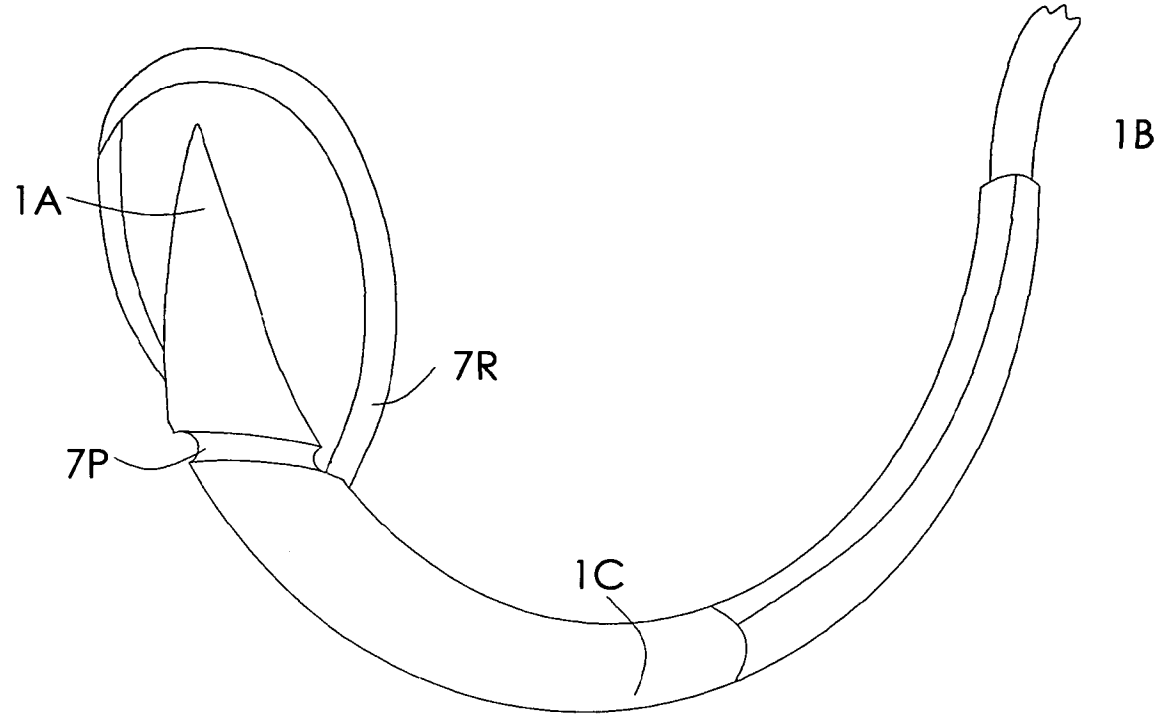


FIG. 7F

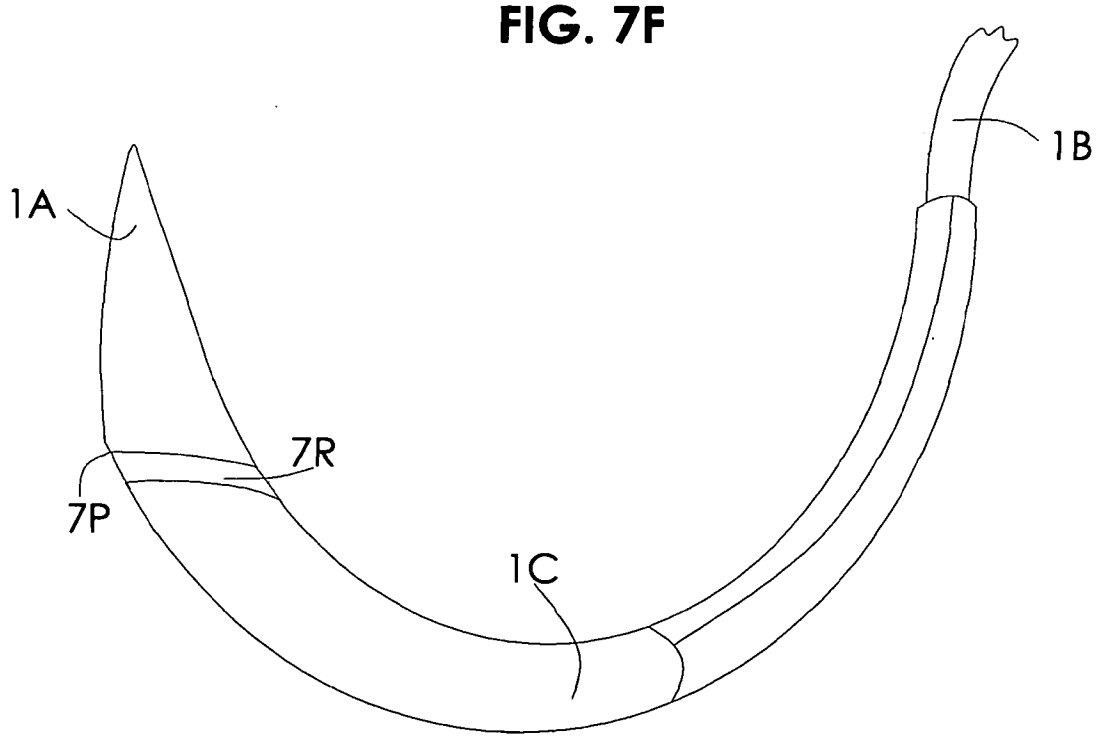


FIG. 7G

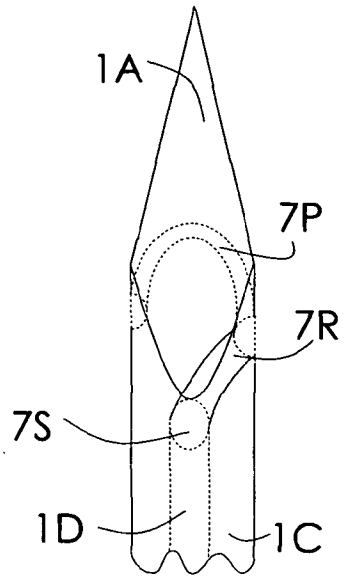


FIG. 7I

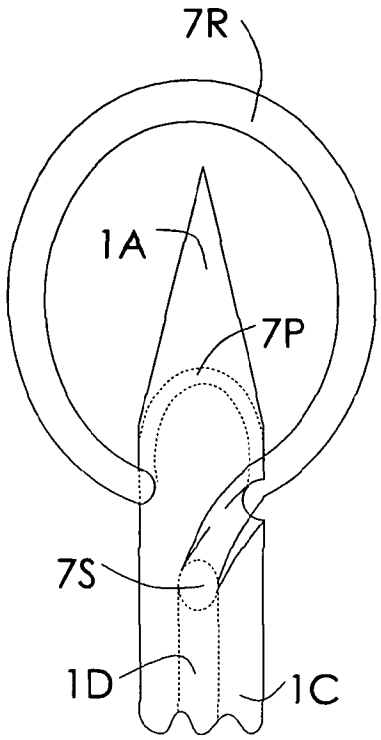


FIG. 7H

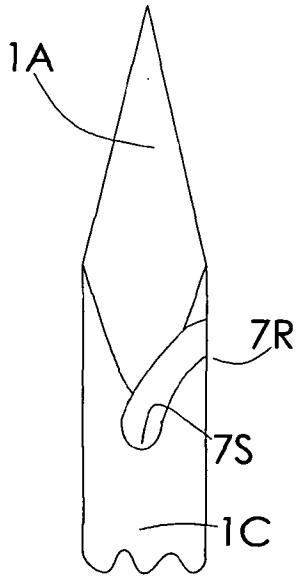


FIG. 7K

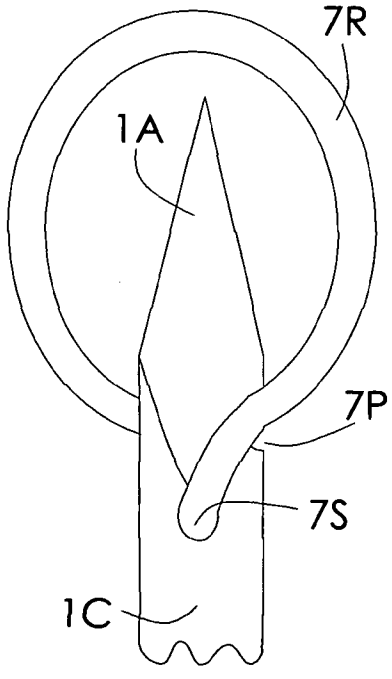


FIG. 7J

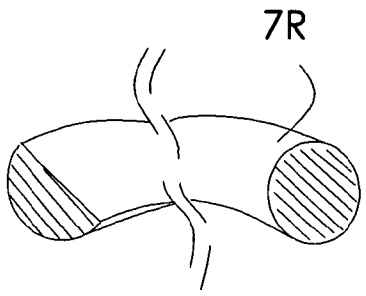


FIG. 7L

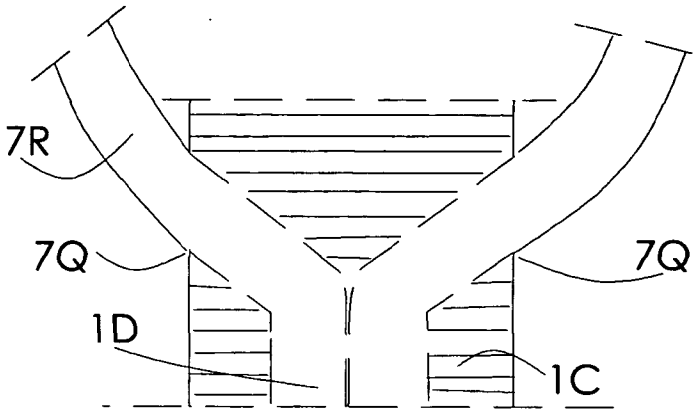


FIG. 7M

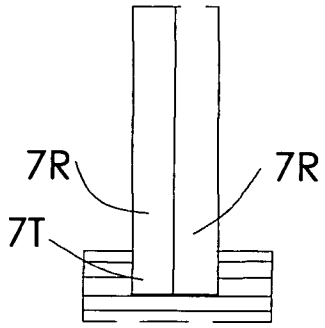


FIG. 7N

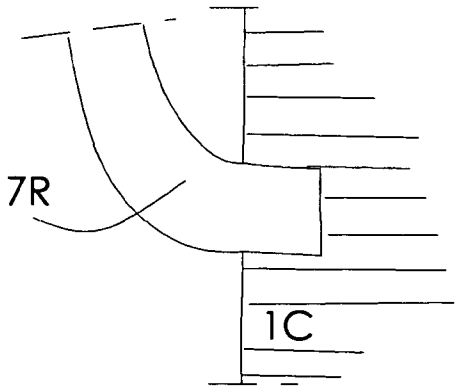


FIG. 7O

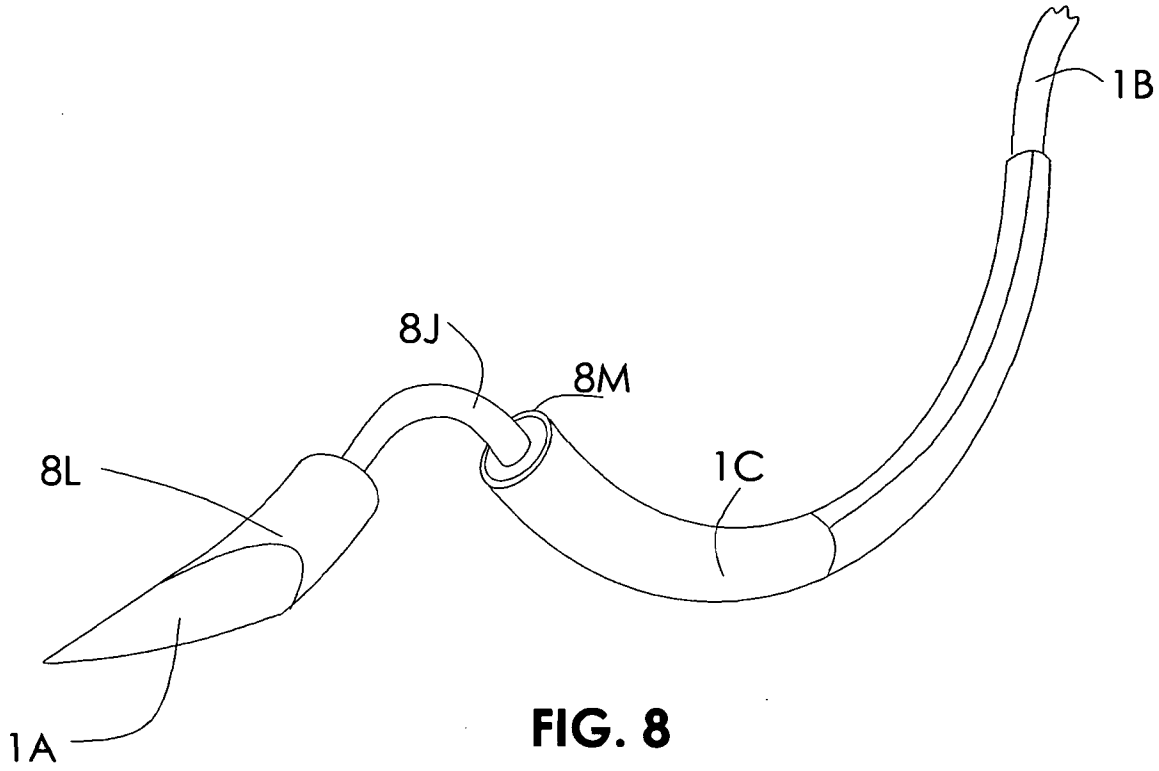


FIG. 8

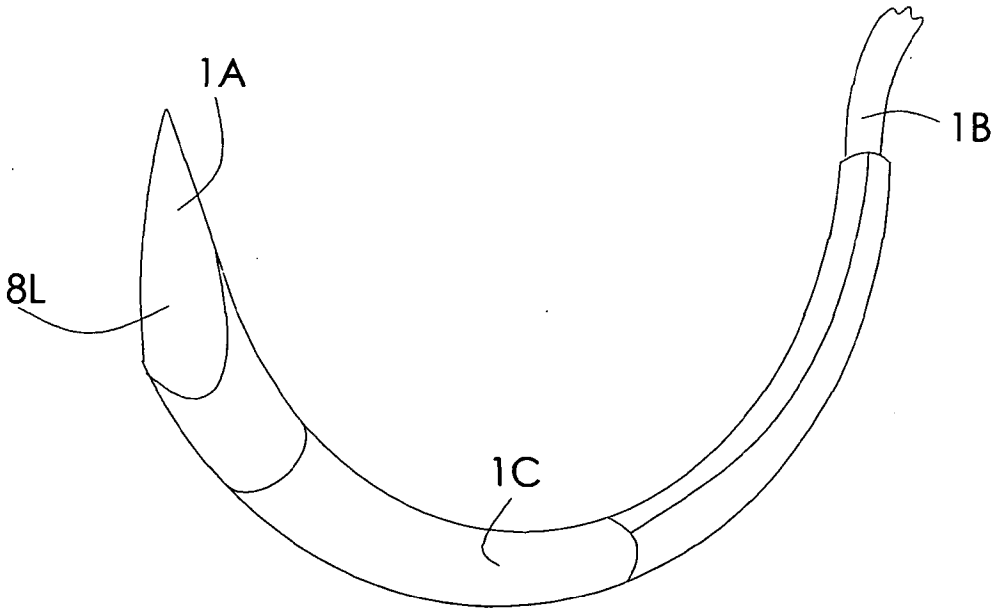


FIG. 8A

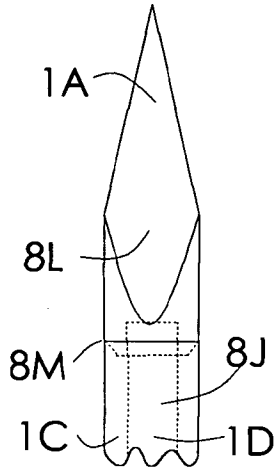


FIG. 8B

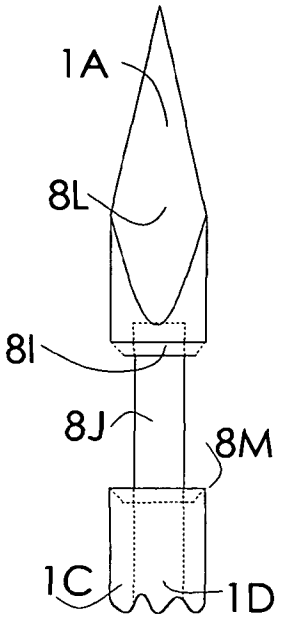


FIG. 8C

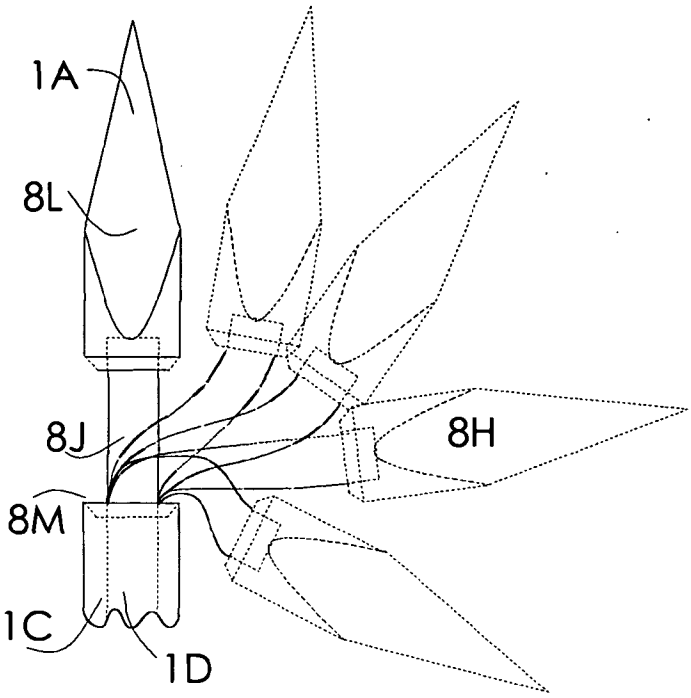


FIG. 8D

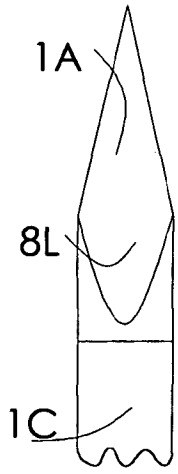


FIG. 8E

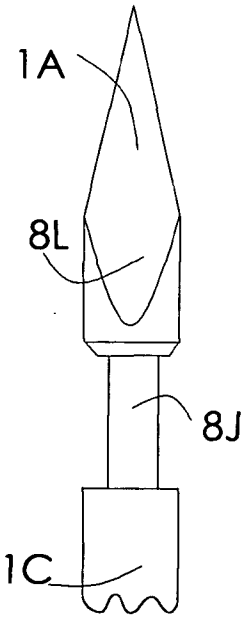


FIG. 8F

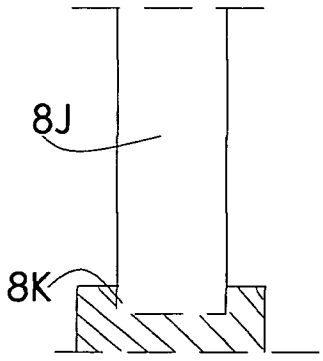


FIG. 8G

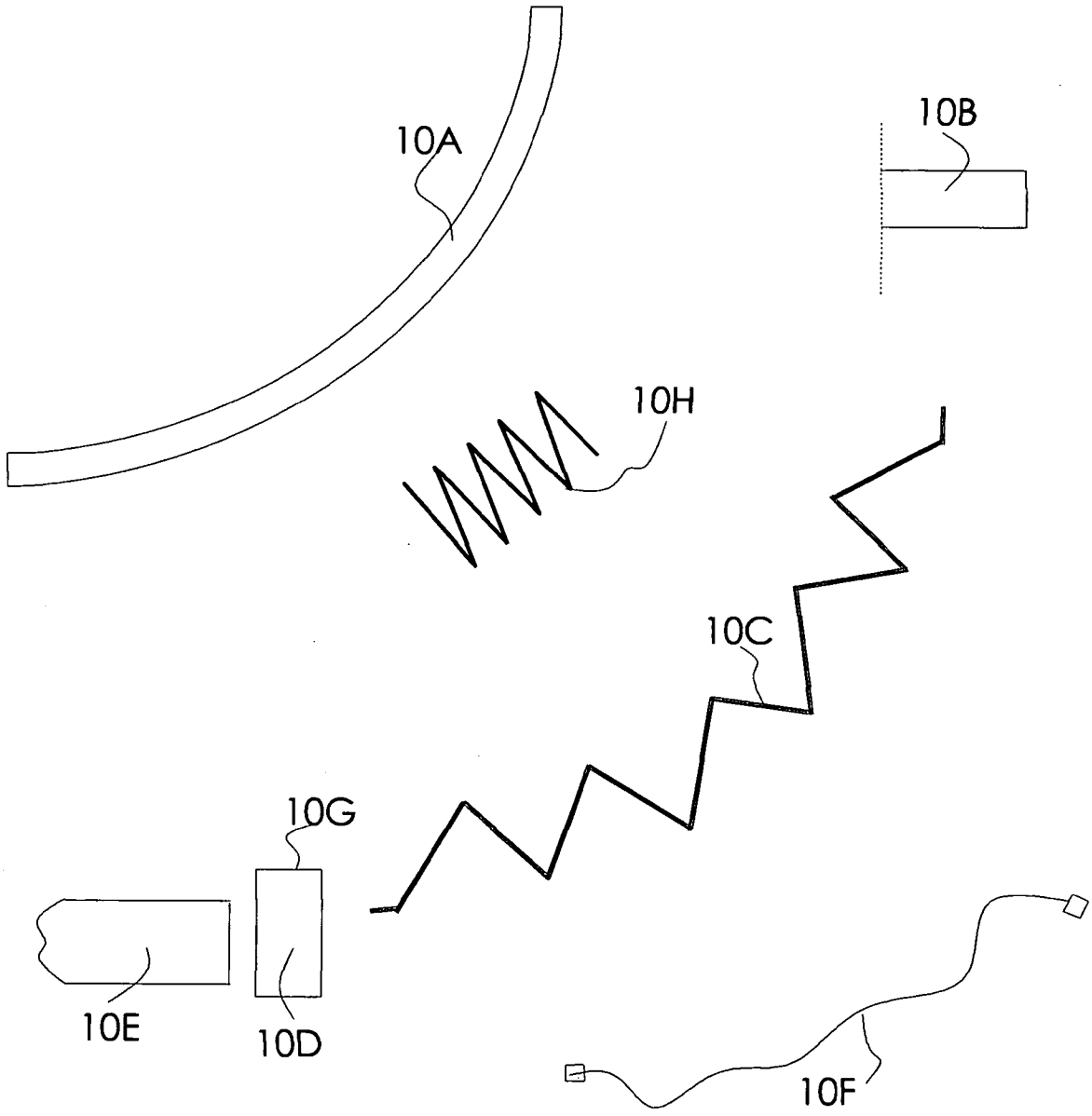


FIG. 10

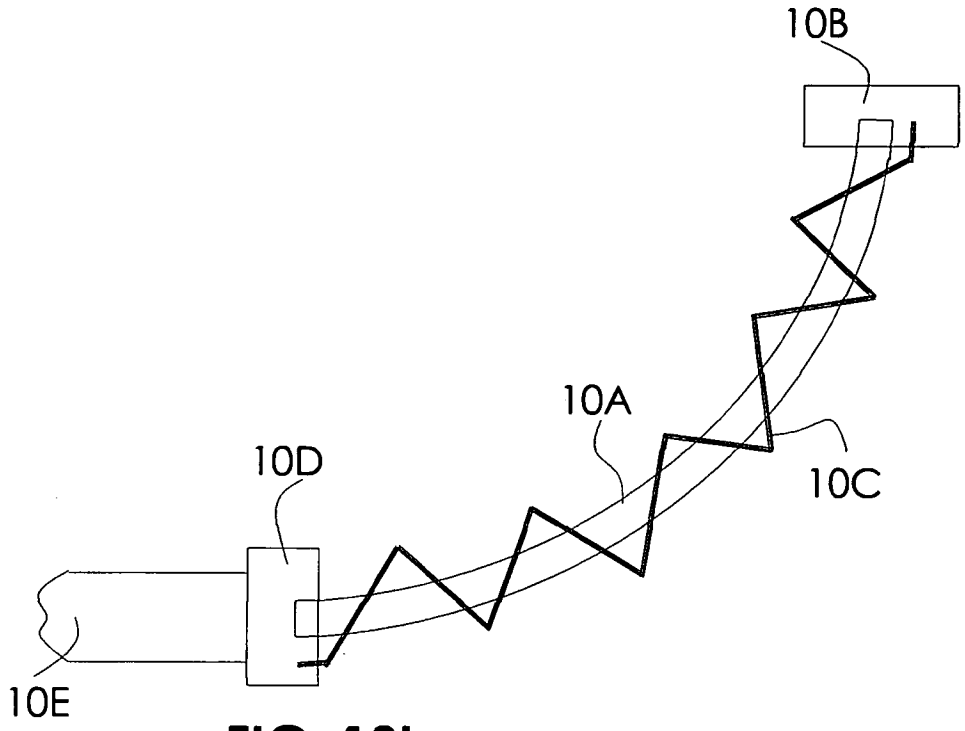


FIG. 10I

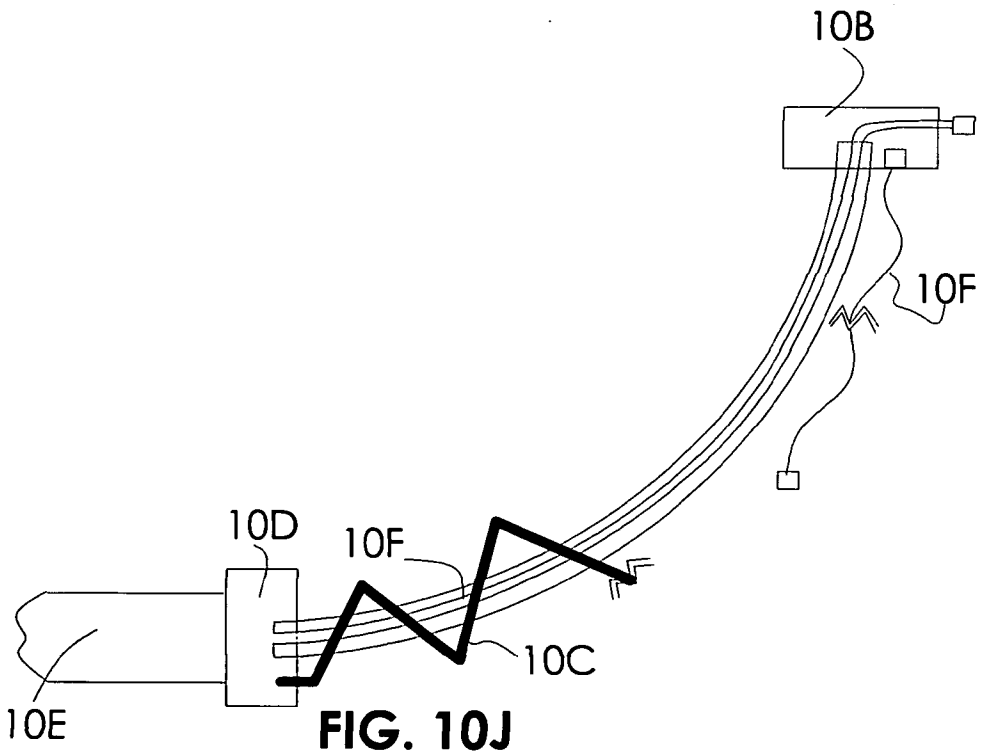


FIG. 10J

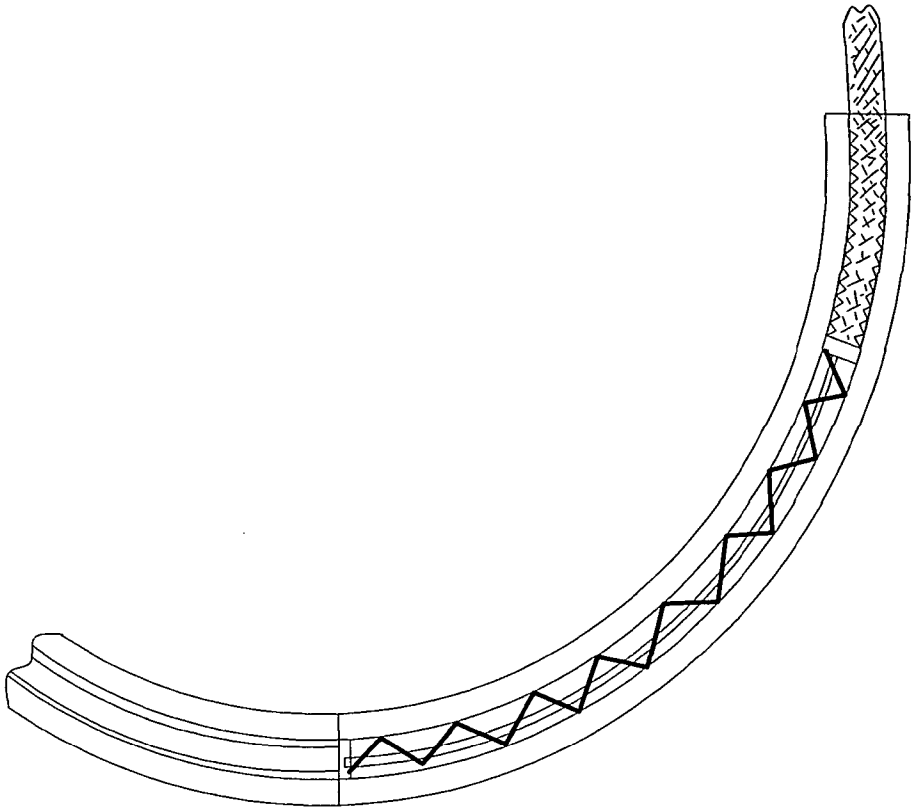


FIG. 10K

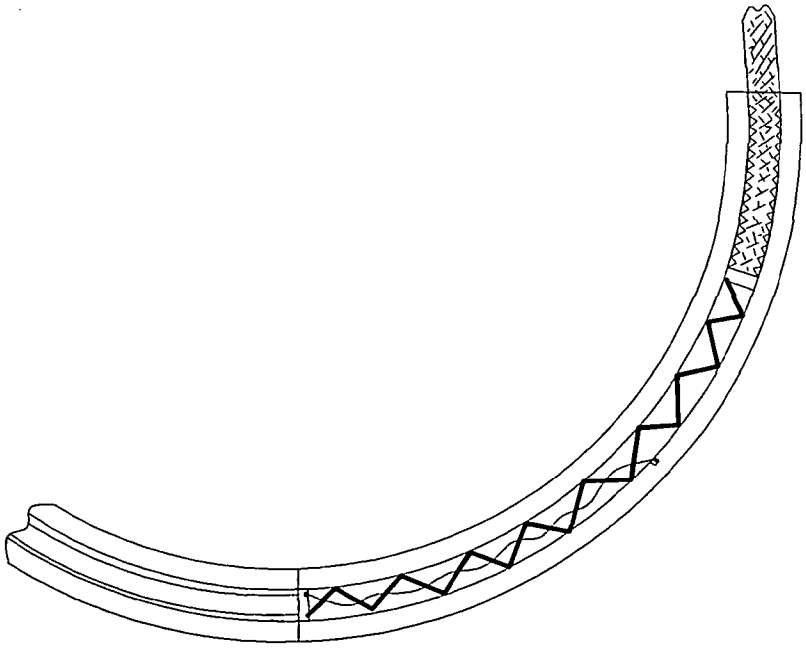


FIG. 10L

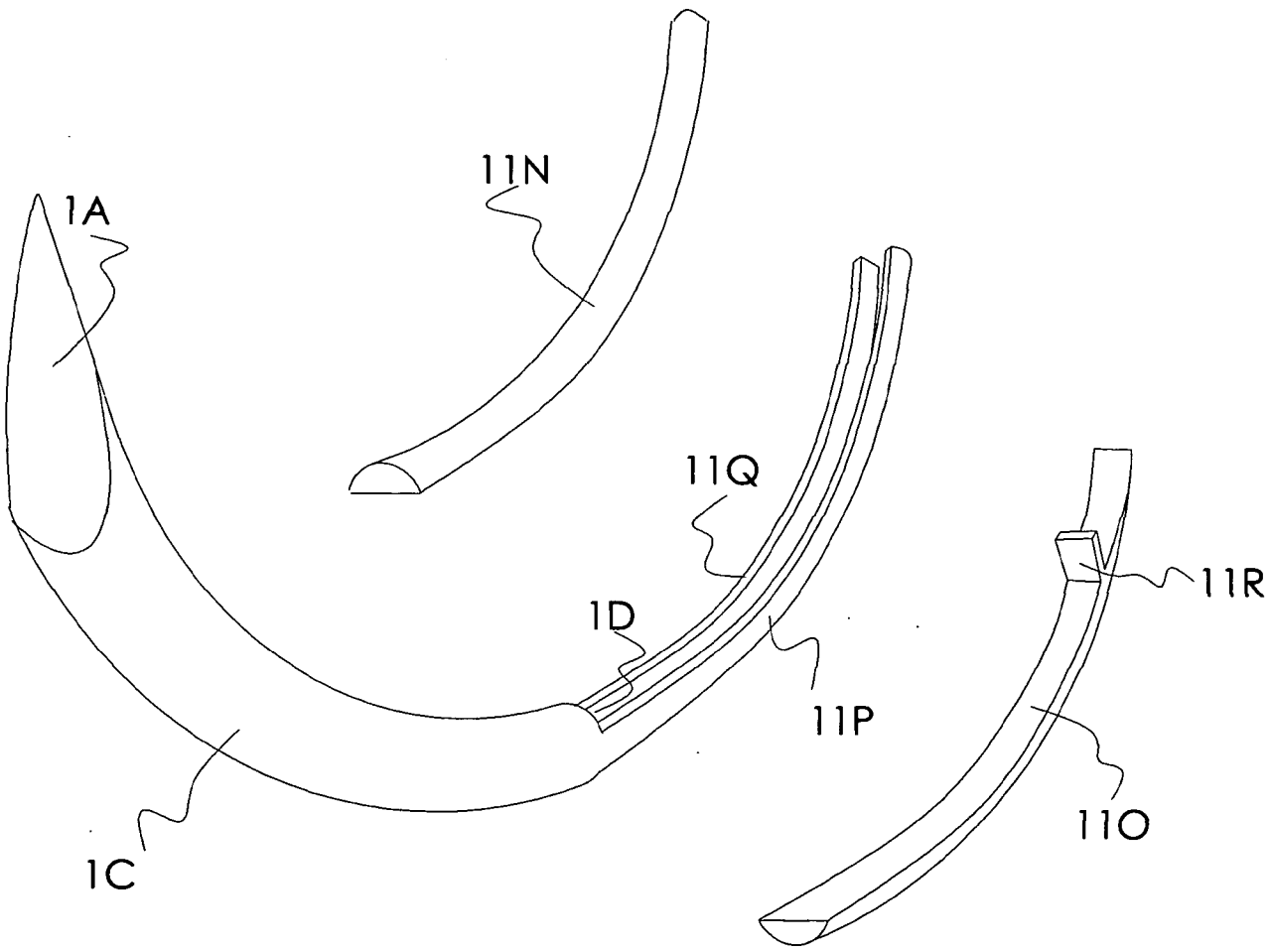


FIG. 11

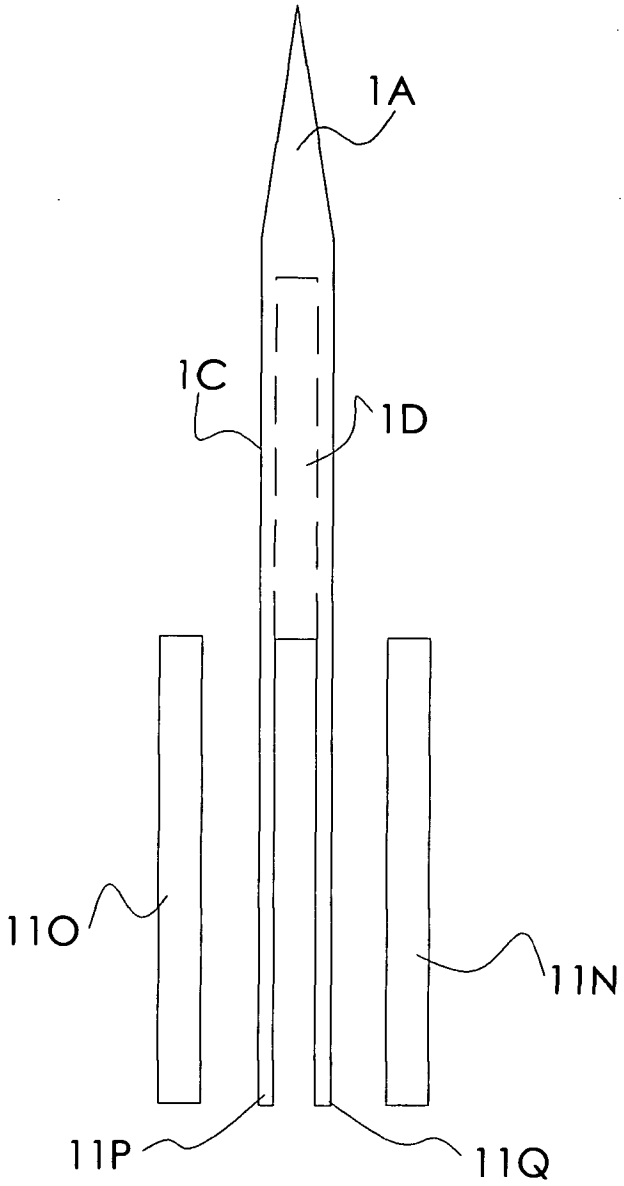


FIG.11A

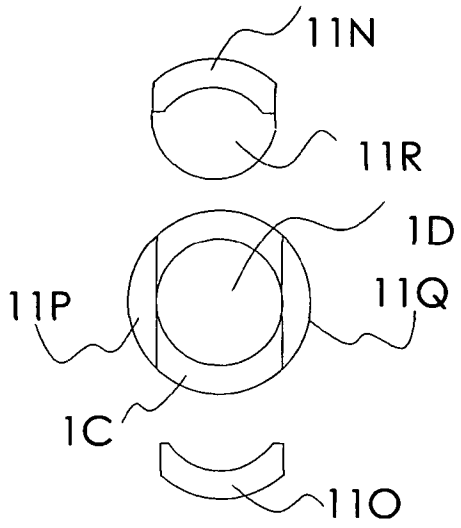


FIG. 11AA

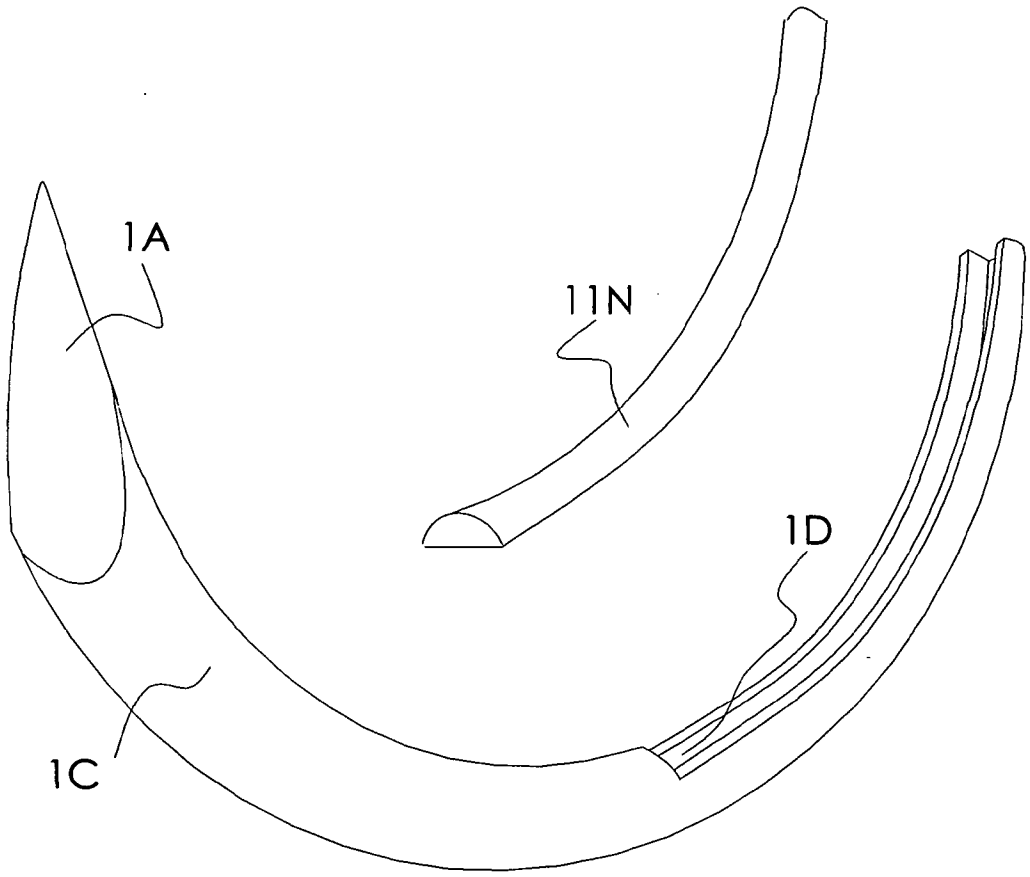


FIG. 11B

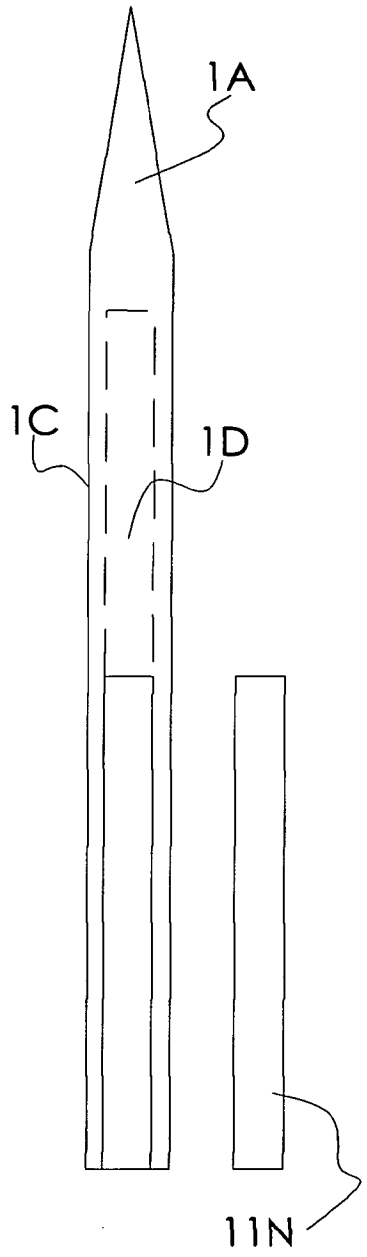


FIG. 11C

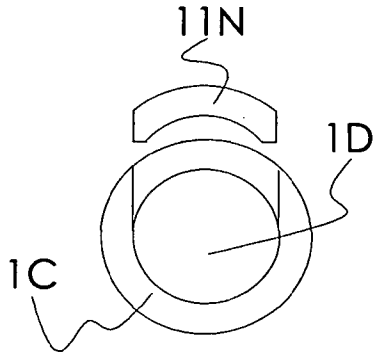


FIG. 11CA

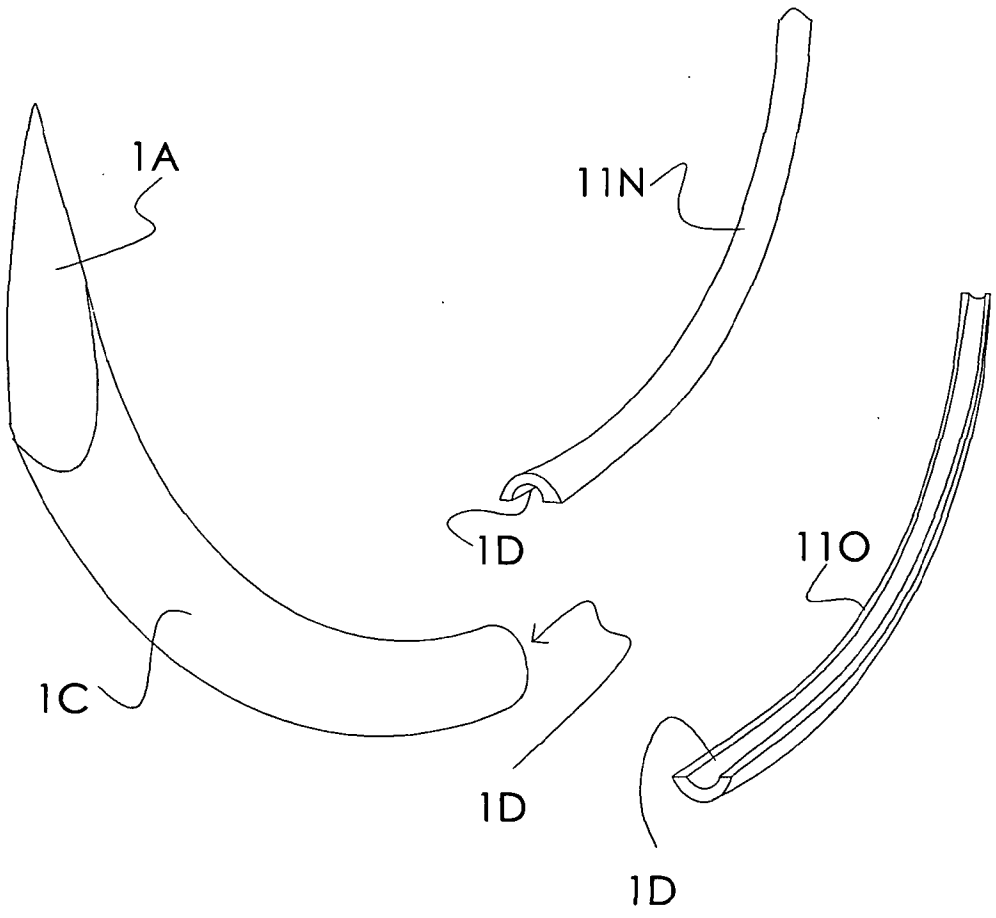


FIG. 11D

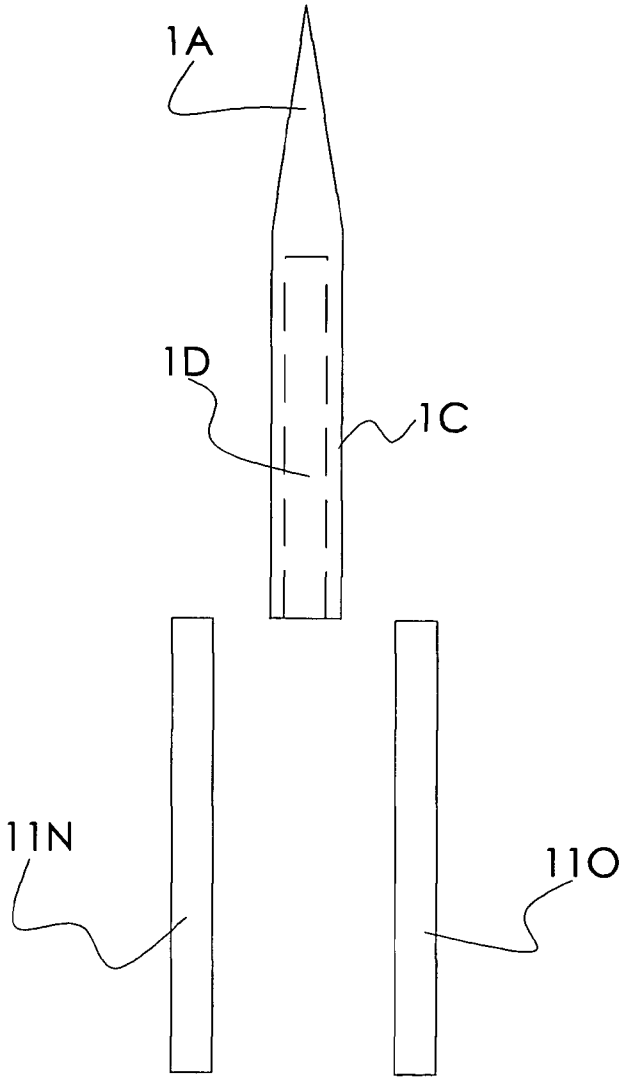


FIG. 11E

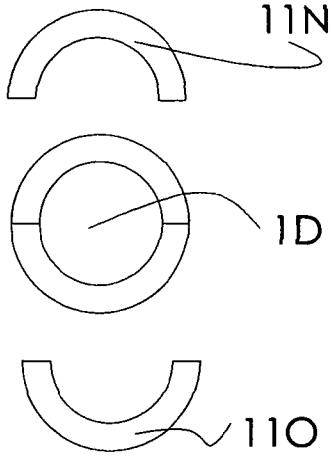


FIG. 11EA

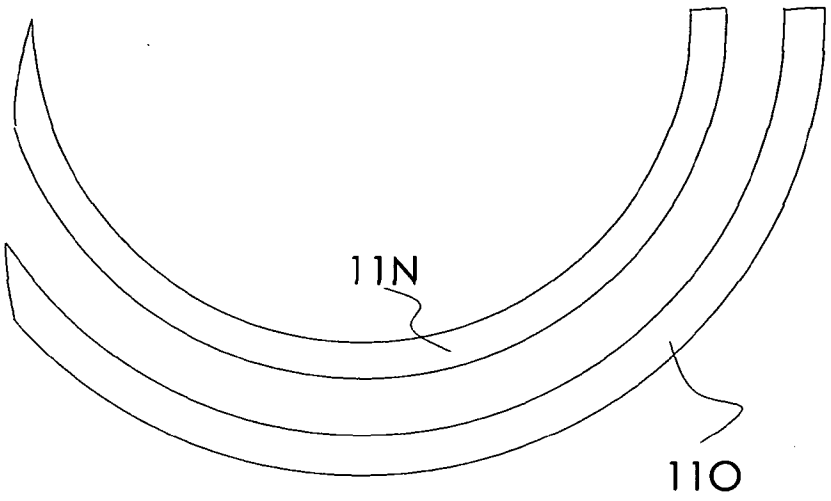


FIG. 11G

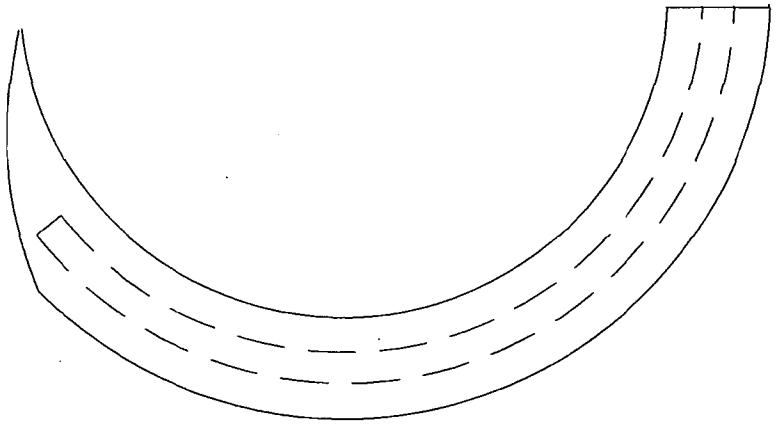


FIG. 11F

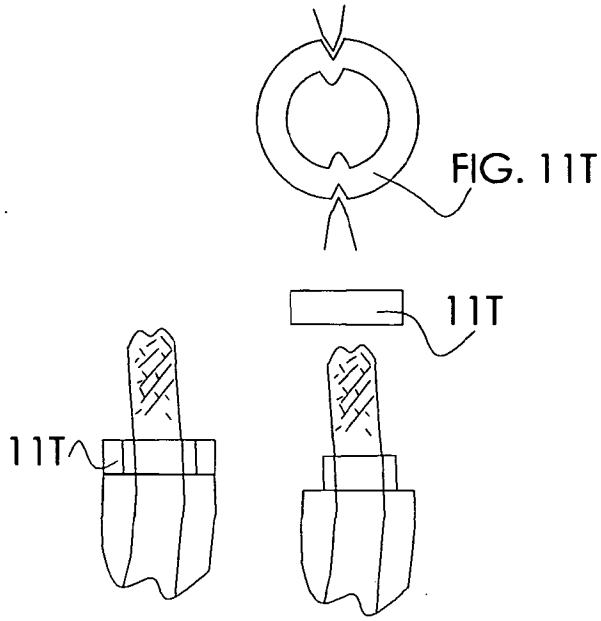


FIG. 11H

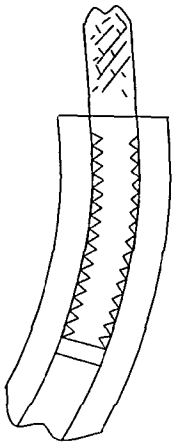


FIG. 11I

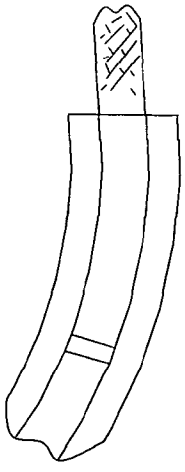


FIG. 11J

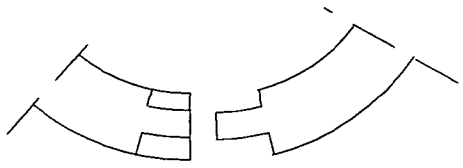


FIG. 11M

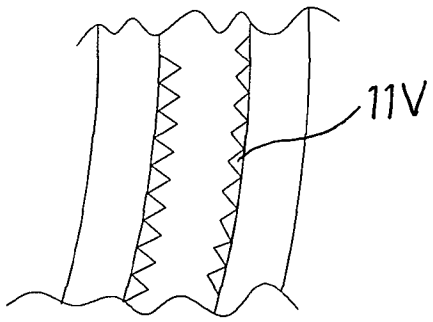


FIG. 11L

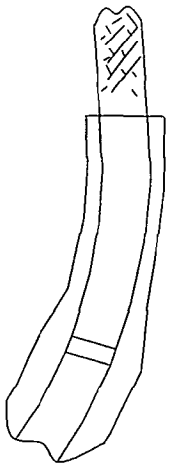
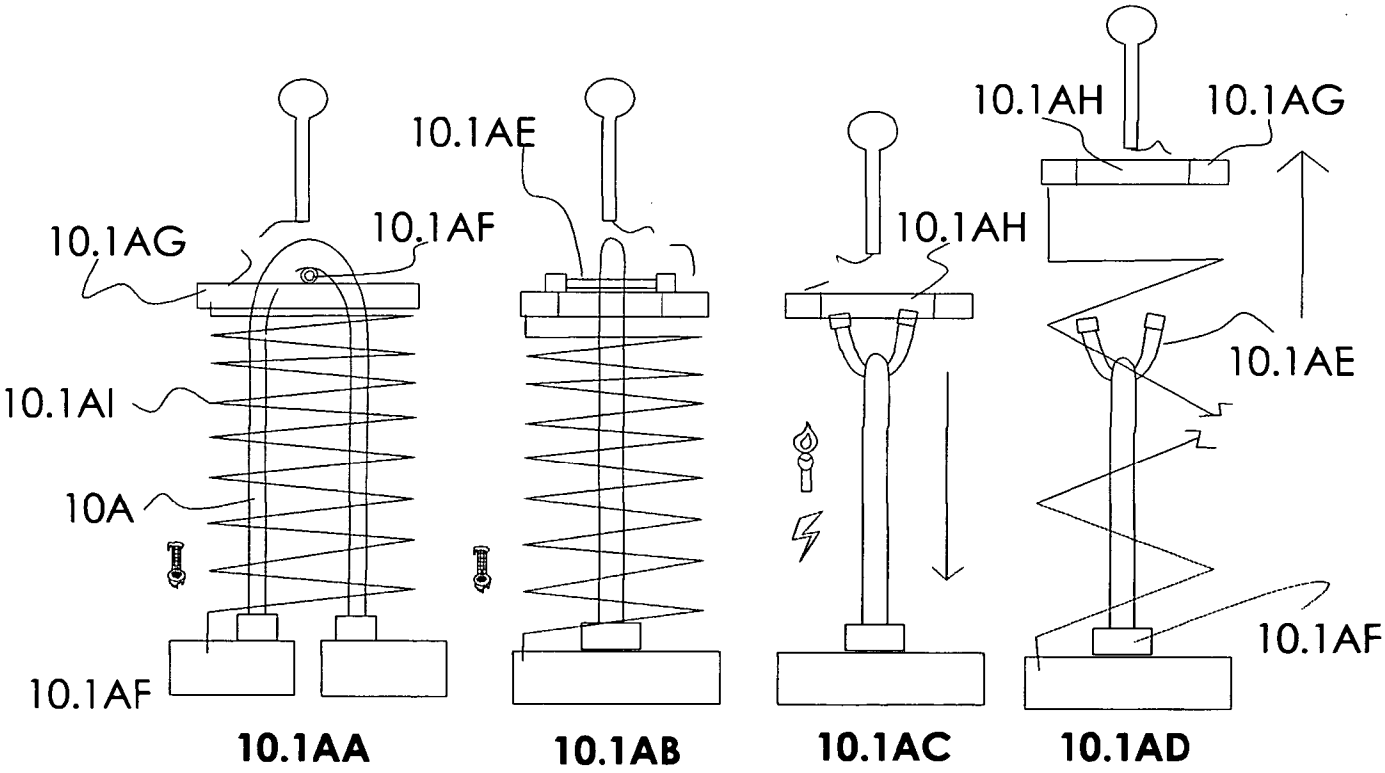


FIG. 11K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10.1AF
10.1AD

FIG. 10.1A

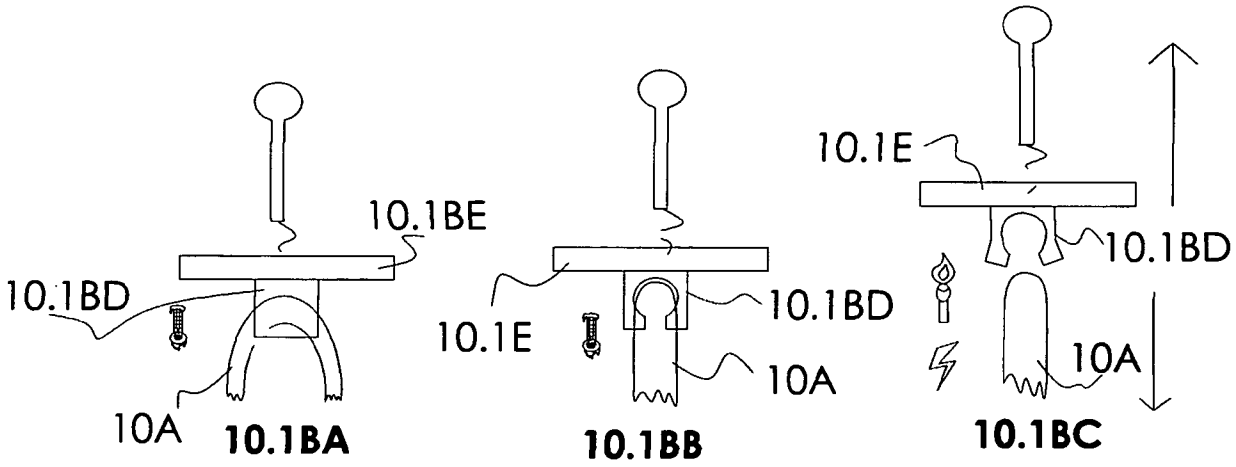


FIG. 10.1B

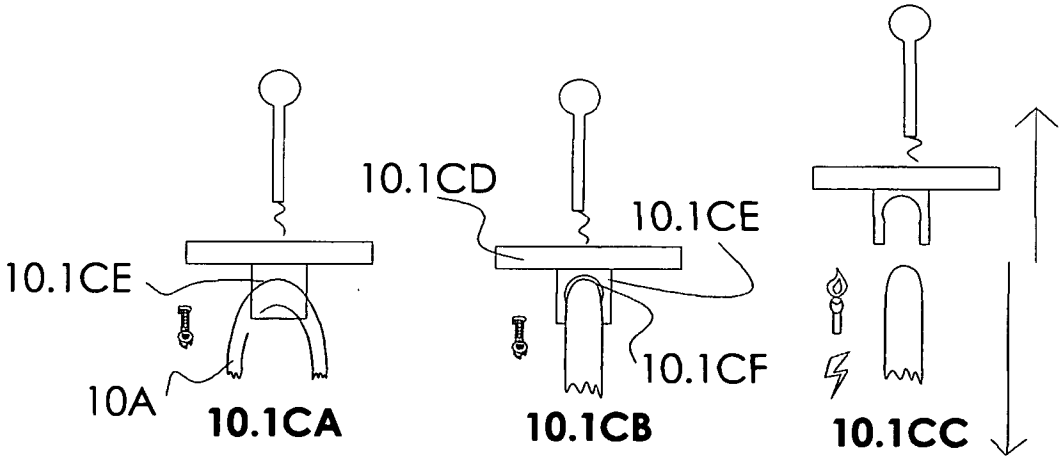
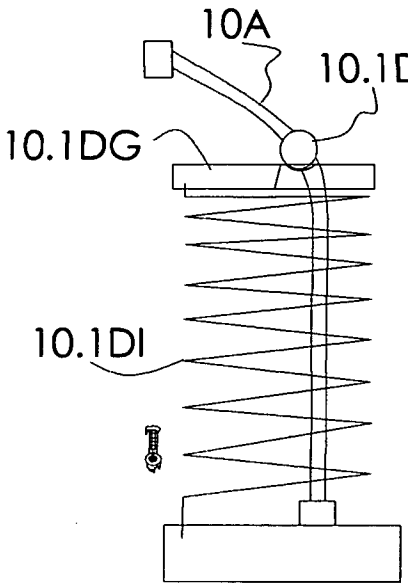
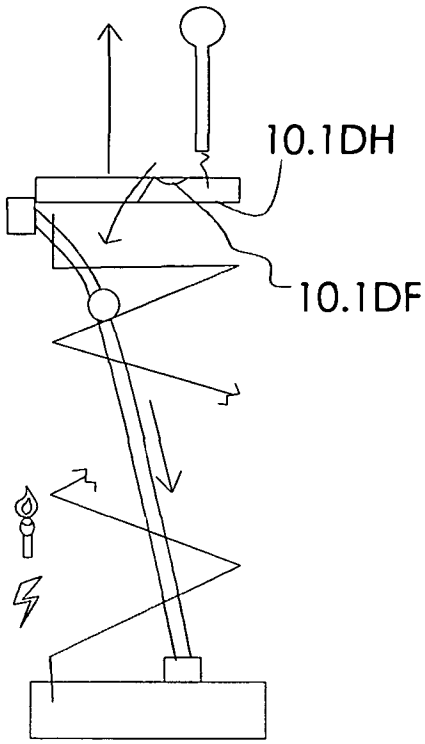


FIG. 10.1C



10.1DA



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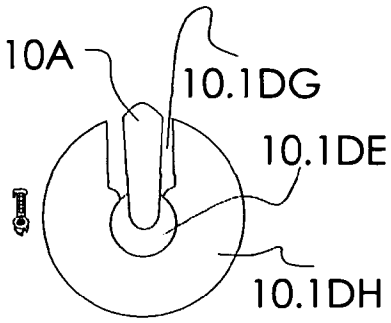
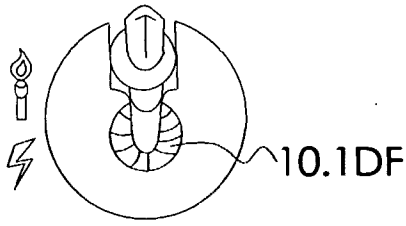
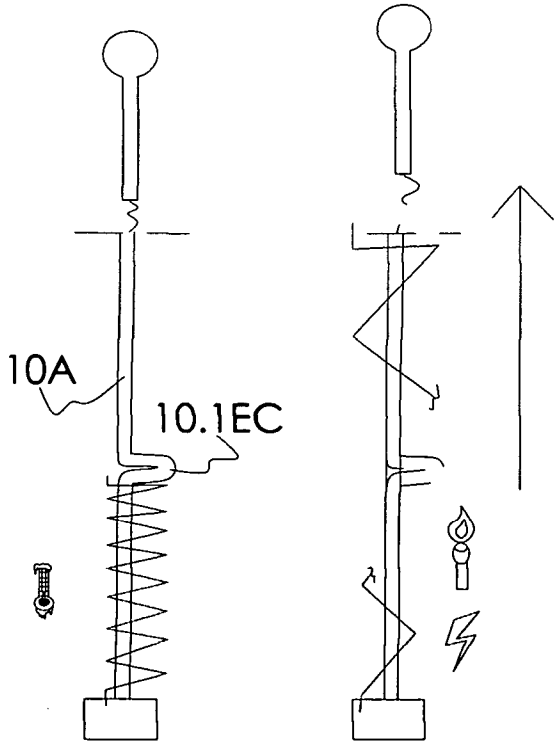


10.1DD



10.1DC

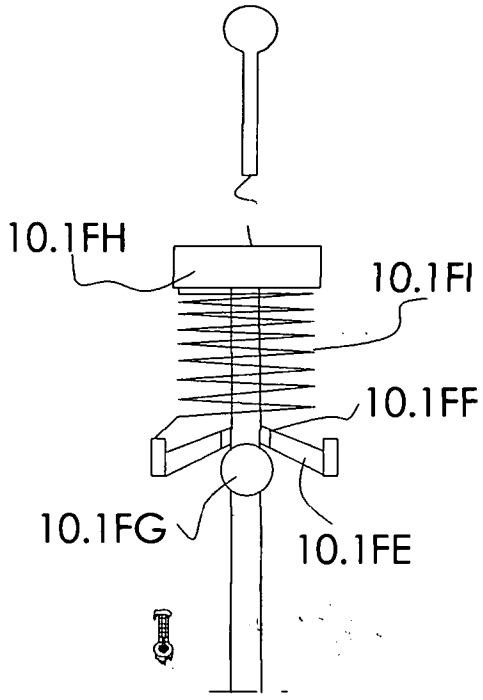
FIG. 10.1D



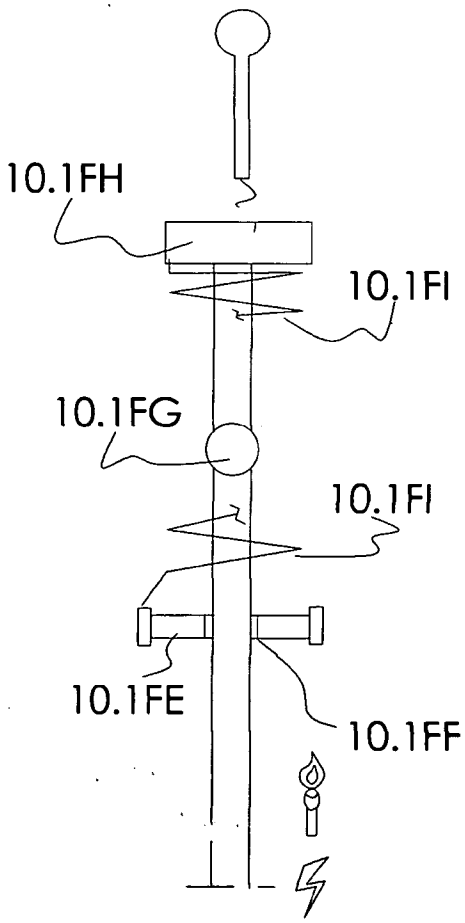
10.1EA

10.1EB

FIG. 10.1E



10.1FA



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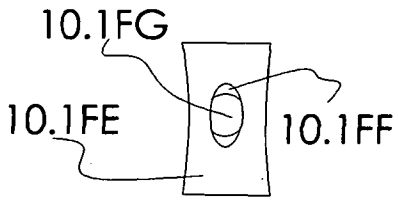
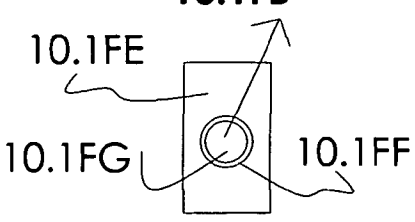


10.1FB



10.1FD

FIG. 10.1F

PTO/SB/09 (10-98)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional)

Applicant or Patentee: Matthew Earl Meyer

Application or Patent No.: _____

Filed or Issued: _____

Title: Safety Suture Needle Assemblies and Means of Activation.

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

☒ the specification filed herewith with title as listed above.

☐ the application identified above.

☐ the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ No such person, concern, or organization exists.

☐ Each such person, concern, or organization is listed below.

Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Matthew Earl Meyer		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
[signature]		
Signature of inventor	Signature of inventor	Signature of inventor
2/8/04		
Date	Date	Date